Boston Scientific
Advancing science for life™

2017

Rhythm Management Product Performance Report

Q4 Edition

CRM Quality Pledge

I improve the quality of patient care and all things Boston Scientific

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q4 2017 report includes data through October 10, 2017.

Boston Scientific provides performance data for pulse generators and leads that meets or exceeds the 2014 revision of ISO 5841-2: 2014 (E), the AdvaMed Industry Guidance for Uniform Reporting of Clinical Performance, and addresses recommendations from the Heart Rhythm Society Task Force.

This report provides the most comprehensive presentation of rhythm management product performance data available, including:

- ✓ U.S. lead and pulse generator survival probability
- ✓ Worldwide malfunction counts and patterns
- ✓ Worldwide malfunctions during an implant procedure
- ✓ Longitudinal Surveillance Registry lead survival probability
- ✓ Acute (first month) lead observations
- ✓ Chronic (after first month) lead complications
- ✓ Reasons for out of service
- ✓ Return rates

Your feedback is always welcome, and plays a vital role in our effort to continuously improve our products and services, advancing science to transform the lives of our patients.

Sincerely,

Renold J. Russie
Vice President, Quality Assurance

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Statistical Methodology

What Is Device Survival Probability?
Medical journals have traditionally used patient survival probability to display information on treatment option effectiveness. In the report, **pulse generator and lead** survival probabilities convey information about long-term performance of implantable cardiac rhythm management products.

Survival probability shows the percentage of implanted devices that remain implanted and in service at various points in a product's service life, in the absence of competing risks, such as natural mortality or voluntary explants. Conceptually, a pulse generator of high reliability and large battery capacity or low current drain remains near 100% survival until eventually, normal battery depletion begins to cause significant numbers of devices to be removed, and the device survival probability drops rapidly. For example, a device survival probability of 99% indicates that within the stated implant duration, the pulse generator had a 1% risk of removal for battery depletion or for incurring a malfunction that required replacement. Survival probabilities are provided with and without normal battery depletions, depicted as “Battery Depletions and Malfunctions” and “Malfunctions Only,” respectively.

Boston Scientific estimates survival probability in compliance with the 2014 revision of international standard ISO 5841-2: 2014 (E). Survival probability is calculated at a given time by separately estimating the probability of surviving each interval and multiplying the survival probabilities of all intervals through which a device has passed. To estimate the probability of surviving any interval, the number of units that successfully functioned during the interval is divided by the number of units exposed to malfunction/depletion during the interval. The number of units exposed is calculated using the actuarial method, where device suspensions in an interval are distributed uniformly across the interval. Reasons for device suspension from survival probability statistics are detailed in the report section entitled U.S. Reason for Out of Service.

Survival probabilities are statistical estimates subject to uncertainty. To quantify this uncertainty, 95% confidence intervals of survival probabilities are computed. Greenwood's formula is used to estimate the standard error of the calculated survival probabilities, and confidence intervals are constructed using a logit transformation, assuming the transformed values are normally distributed. For example, 99.36% (-0.3/+0.2) represents an interval of 99.06% to 99.56%, and these intervals are constructed such that 95% of the time they will contain the true survival probability. These confidence intervals are not symmetric due to the transformation method described previously.

Inclusion Criteria for Pulse Generator and Lead Survival Probability Datasets
Pulse generator survival probability is reported for U.S. implanted devices in product families which meet inclusion criteria described below. Lead survival probability is reported for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry, for product families which meet inclusion criteria described below.

To be included in survival probability statistics, a device must first be successfully implanted (defined in this report as occurring upon pocket closure). Prophylactic device removals are tracked as part of the active population up until the time the device is removed from service; devices removed prophylactically which are not identified as malfunctions at the time of explant do not contribute to a reduction in survival probability. Reasons for device explant or out of service, if known, are provided in this report for each pulse generator product/product grouping.

Survival probabilities are based on devices registered as implanted in the United States. Privacy laws in many other geographies preclude manufacturers from obtaining specific patient implant and explant information, thus device survival probabilities cannot be constructed from these data. Boston Scientific believes, however, that U.S. experience is generally representative of worldwide performance. The Malfunction Details for leads and pulse generators reflect worldwide malfunctions, inclusive of U.S. data.

Criteria for inclusion of product families in this report are in compliance with the AdvaMed *Industry Guidance for Uniform Reporting of Clinical Performance of Pulse Generators and Leads*. Survival estimates are provided for product families once they have at least 10,000 cumulative U.S. implant months. The minimum interval sample size is 200 U.S. implanted units. Pulse generator product families with less than 500 total remaining estimated active U.S. devices are not included in this report. Lead product families that received original U.S. market release approval twenty or more years ago are not included in this report. Survival estimates for leads enrolled in the Longitude Surveillance Registry are provided for product families once they have at least 200 enrolled leads. The minimum interval sample size is 50 leads which have been followed for at least 6 months.

Estimated Longevity information is provided for pulse generator products in the U.S. Survival Probability - Battery Depletions and Malfunctions graphs, depicted as a blue bar on the x axis for Years Implanted. The estimated longevity values from the Instructions for Use for each product family are used to construct the blue longevity bars on their U.S. Survival Probability graph. They represent the range of estimated longevity based on a variety of programmed settings and therapy usage.

Survival probability data are presented in tabular and graphical formats online at www.bostonscientific.com/ppr. Performance data for Intermedics products may also be found on www.bostonscientific.com/ppr. Specific inclusion criteria for pulse generator and lead survival probability datasets are described here. Not all products may be approved for use in all geographies, as product approval is geography specific.

Worldwide distribution, U.S. registered implant and U.S. estimated active implant numbers have been rounded to provide population size context.

To convey implant experience for a product family, average device age and U.S. approval date are provided. The U.S. approval date listed is the earliest date Boston Scientific received approval for one or more of the models in the family. For Longitude Surveillance Registry data, the number of enrolled leads and their cumulative followup months are also provided for context.

Survival Probability – Battery Depletions and Malfunctions (Pulse Generators)
Reduction in survival probability for **pulse generators** is due to:

- Devices removed for normal battery depletion
- Device malfunctions occurring while implanted, as confirmed by returned product analysis
- Devices removed from service and reported to have exhibited premature battery depletion, but not confirmed by laboratory analysis, whether returned or not—also known as “unconfirmed reports of premature battery depletions.”

Survival Probability – Malfunctions Only (Pulse Generators)
Reduction in survival probability for **pulse generators** is due only to:

- Device malfunctions occurring while implanted, as confirmed by returned product analysis; premature battery depletions are considered device malfunctions.

In this case, normal battery depletions do not contribute to the reduction in survival probability; rather, reduction in survival probability is due only to confirmed pulse generator malfunctions. Furthermore, unconfirmed reports of premature battery depletions do not reduce “Malfunctions Only” survival probability. Put another way, this information depicts the percentage of confirmed malfunction-free devices remaining in service at various intervals in the product's service life, based on returned product analysis.

Survival Probability — Complications and Malfunctions (Leads)
The 2014 version of ISO 5841-2: 2014(E) outlines a methodology for lead survival probability inclusion. Boston Scientific has applied this methodology for survival probability to all lead families being implanted as of May 2009 and forward. Worldwide malfunctions are not included for older lead families.

Reduction in survival probability is due to:

- Leads and lead segments returned for analysis and determined to be non-compliant in form, fit, or function at any time while implanted
- Leads removed from service with reported complications 30 days or more post-implant, whether returned or not. See the Chronic Lead Complications Table in this report for the observations which are included.

Further Adjustments for Device and Lead Survival
Because underreporting of patient deaths unrelated to device function would result in overestimation of pulse generator or lead survival by overstating the number of devices in service, Boston Scientific addresses this underreporting in two ways. First, regular updates are obtained from the Social Security Administration about deceased persons and compared to Boston Scientific patient data to learn about patients who have died but whose deaths had not been reported to Boston Scientific. Second, Boston Scientific uses 10% annual patient mortality as a baseline and adjusts reported patient deaths in any interval for which reports are less than the baseline rate. No adjustment is applied to account for underreporting of malfunctions, as the rate of underreporting is unknown.

Boston Scientific does not make statistical adjustments to account for underreporting of battery depletion. However, as mentioned earlier, Boston Scientific includes non-returned devices removed from service for battery depletion with no associated complaint as normal battery depletions.

Categorization of Malfunctions for Survival Probability Reporting
Malfunctions represent pulse generators and leads removed from service and confirmed through laboratory analysis to have operated outside the specified performance limits established by Boston Scientific while implanted and in service. Device damage occurring during or after explant, or caused by external factors including those warned against in product labeling (such as ionizing therapeutic radiation), are not reported as device malfunctions in survival data. Damage to a pulse generator caused by a lead malfunction is reported as a lead malfunction. Malfunctions are further classified according to their impact on therapy, as follows:

Malfunction With Compromised Therapy —
The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service.

Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; intermittent malfunction in which therapy is compromised while in the malfunction state.

Malfunction Without Compromised Therapy —
The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here.

Examples include (but are not limited to): error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes the battery to lose power quickly enough to result in premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Categorization of Normal Battery Depletion for Survival Probability Reporting
Per the AdvaMed *Industry Guidance for Uniform Reporting of Clinical Performance of Pulse Generators and Leads*, **Normal Battery Depletion** is defined as the condition when

a) A device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or

b) A device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using actual device settings and therapeutic use.

Boston Scientific includes within this count both returned *and non-returned* devices removed from service for battery depletion with no associated complaint. In conformance with the AdvaMed guidance document, Boston Scientific performs battery usage analysis, including battery status verification, on all devices returned without a complaint. We continue to include non-returned devices reported by our customers as being removed from service due to normal battery depletion within this count.

Boston Scientific CRM's Corrective and Preventive Actions (CAPA) System

Boston Scientific strives to provide implantable devices of high quality and reliability. However, these devices are not perfect and may exhibit malfunctions at a low rate of occurrence. Device performance information is received from many sources through various channels. Boston Scientific monitors information from many sources including suppliers, testing, manufacturing and field performance to identify opportunities for improvement.

When a device is returned to Boston Scientific, laboratory technicians and engineers assess overall device function and perform analysis using specific tests related to the clinical observation(s). Test results are compared to original manufacturing records and design intent. Clinical observations are added to laboratory findings to help determine root cause of the clinical observation(s). Each discrete event is then compared to other similar-appearing events. If a pattern is detected, actions are taken to identify a common root cause, and improvements intended to improve product reliability and/or performance may be implemented. Observations from supplier data and internal manufacturing operations also lead to opportunities for improvement. Improvements, when made, may include design changes in existing or subsequent generations, manufacturing and supplier process modifications, software updates, educational communications, and/or labeling changes as examples. Improvement implementation may vary by geography due to various factors including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern, and may not mitigate or eliminate the potential for additional malfunctions. In cases where an improvement is made to an approved product line, devices made without the improvement may continue to be distributed where such products meet our high reliability and performance standards, particularly when changes are incremental and in accordance with our overall philosophy of continuous product improvement.

Improvements are closely monitored for effectiveness. Boston Scientific informs regulatory bodies of each significant event that poses potential risk to patient health to meet regulatory obligations, and shares returned product investigation findings with physicians. The malfunction details section for pulse generators and leads includes a summary of these findings.

In summary, thorough investigation of internal and external data coupled with low trigger levels for improvements creates a continuous product improvement system that is very responsive to patient and physician needs. Boston Scientific is committed to characterizing and presenting to our customers an accurate picture of product performance and addressing identified issues in a timely fashion.

Malfunction Details: Overview

Boston Scientific CRM pursues product quality and reliability with a passion. We therefore continuously monitor product performance to make improvements whenever possible. Worldwide Malfunction tables provide a count and description of malfunctions associated with the majority of actively in-service Boston Scientific products. Intermedics co-branded product data are included in corresponding pacemaker and pacing lead malfunction counts and details. Information presented is based on malfunctions reported to and analyzed by Boston Scientific. Each table contains malfunction counts listed by category, pattern and therapy availability.

Category
Malfunctions are categorized by the nature of their root cause. For example, a malfunction due to the software within a pulse generator is listed in the Software category. There are four pulse generator malfunction categories and four malfunction categories for leads (described below).

Patterns
Patients and physicians have asked for more access to Quality System details; therefore, we provide information on patterns of product performance. Patterns listed are informational and do not represent actions that need to be taken. Boston Scientific is committed to direct communication when predicted product performance fails to achieve design or performance expectations or when actions may be taken to improve patient outcomes. Malfunctions associated with product advisories are denoted. Refer to the Product Advisories section for more information.

Each pattern description includes:

- ***Clinical Manifestation and Root Cause*** – Malfunctions for each product are characterized according to root cause. Descriptions provide clinical observations and/or analysis findings associated with each malfunction pattern listed in this report. Malfunctions listed within “Other” either do not yet have an identified root cause, or are related to a proprietary product feature, such as connectors or seal rings.

- ***Improvement Implementation*** – All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, improvements have been or will be implemented in response to identified malfunction patterns. Improvements may include product design changes in existing or subsequent generations, manufacturing process modifications, software updates, educational communications or labeling changes. Improvement implementation may vary by geography due to various factors, including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern, and may not completely mitigate or eliminate the potential for additional malfunctions.

Pattern information in this report is dynamic. Pattern names, superscript number assignments and descriptions may all change from quarter to quarter; as Boston Scientific's investigations progress and improvements are implemented, updated information is provided.

Therapy Availability
Malfunctions are further classified according to their impact on therapy, as follows:

- ***Malfunction With Compromised Therapy*** – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; intermittent malfunction in which therapy is compromised while in the malfunction state.

- ***Malfunction Without Compromised Therapy*** – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here. Examples include (but are not limited to): error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes the battery to lose power quickly enough to result in premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Pulse Generator Malfunctions
Pulse generator malfunctions represent devices removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. Device damage occurring during or after explant, or caused by external factors including those warned against in product labeling (e.g. therapeutic radiation), are not considered device malfunctions. Damage to a pulse generator caused by a lead malfunction is reported as a lead malfunction.

Lead Confirmed Malfunctions
Lead confirmed malfunctions represent leads removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. The Boston Scientific Product Performance Report is in compliance with the 2014 version of ISO 5841-2: 2 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. This version categorizes leads with reported complications which are taken out of service and returned, but for which no malfunction can be confirmed, as Chronic Lead Complications. This methodology also addresses the Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines.

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Supporting Greater Return of Explanted Devices

The Heart Rhythm Society (HRS) Task Force on Device Performance Policies and Guidelines stated that knowledge, confidence, and trust in cardiac rhythm management devices can be strengthened through enhancing systems that increase the return of devices to the manufacturer. Boston Scientific CRM shares in this belief and supports the HRS-specified actions geared toward achieving the goal of greater device return to the manufacturer, including post-mortem device interrogation, explantation and return to the manufacturer.[1]

In this section of the report, Boston Scientific provides device return rate data with the goal of raising awareness and improving current device explant and return rates. Figure 1 on the following page depicts the percentage of devices reported to have been explanted and then returned to Boston Scientific for various product therapy types.

Help Us Provide You With More Complete Product Performance Data

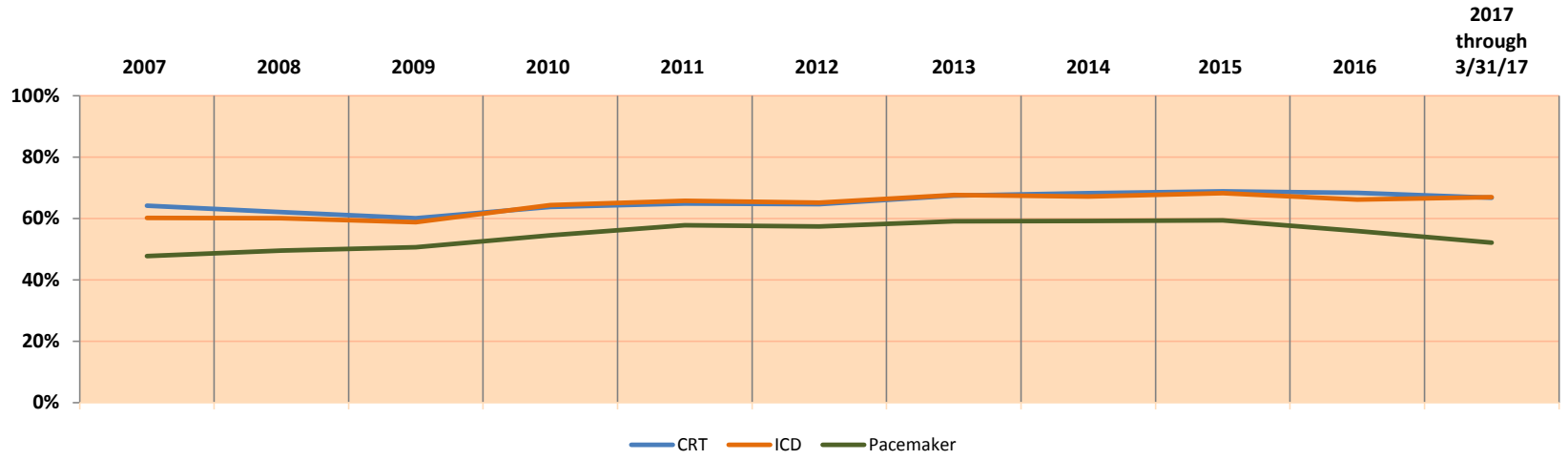
Reporting Adverse Events

The data in this report reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department at:
United States: Phone 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698.
International: Please refer to the Country Offices List for local contact information.
E-mail: crmevent@bsci.com

Returning Products to Boston Scientific

Boston Scientific provides a Returned Products Kit (Model 6499) that includes proper forms, shipping/packaging (biohazard bags), and a prepaid shipping label. It can be ordered at no charge through Boston Scientific's Customer Service department at 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698, or you can order a Returned Products Kit online at www.bostonscientific.com/ppr.

[1]Carlson et al. Recommendations from the Heart Rhythm Society Task Force. Heart Rhythm. October 2006; 3(special issue):1251 — 1252.



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017 through 3/31/17
Explants	4248	5681	9268	10487	9328	8058	8337	6928	5064	4607	1324
Returns	2726	3529	5568	6691	6055	5211	5623	4731	3489	3151	884
% Returned	**64%**	**62%**	**60%**	**64%**	**65%**	**65%**	**67%**	**68%**	**69%**	**68%**	**67%**
Explants	11541	15559	19505	19938	16585	11986	11922	11292	10016	8374	2014
Returns	6952	9350	11469	12835	10913	7816	8074	7588	6839	5546	1350
% Returned	**60%**	**60%**	**59%**	**64%**	**66%**	**65%**	**68%**	**67%**	**68%**	**66%**	**67%**
Explants	18416	20466	21019	21133	20023	18714	18815	19327	19671	19425	4990
Returns	8792	10149	10643	11524	11584	10747	11120	11445	11681	10875	2600
% Returned	**48%**	**50%**	**51%**	**55%**	**58%**	**57%**	**59%**	**59%**	**59%**	**56%**	**52%**

Figure 1. Percentage of U.S .explanted devices as reported and returned to Boston Scientic CRM.

RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

Models G124/G125/G126/G128/G138/
G224/G225/G228/G237/G247/
G248/G324/G325/G347/G348/
G424/G425/G426/G428/G437/
G447/G448/G524/G525/G526/
G528/G537/G547/G548

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D
**Models G124/G125/G126/G128/G138/
G224/G225/G228/G237/G247/
G248/G324/G325/G347/G348/
G424/G425/G426/G428/G437/
G447/G448/G524/G525/G526/
G528/G537/G547/G548**

Worldwide Distribution: 2,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

AUTOGEN CRT-D

Models G160/G161/G164/G166/G168/
G172/G173/G175/G177/G179

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

AUTOGEN CRT-D
Models G160/G161/G164/G166/G168/ G172/G173/G175/G177/G179

Worldwide Distribution: 21,000
Worldwide Confirmed Malfunctions: 12

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**1**	**8**
[61] High voltage circuit component	4	-	
[62] Integrated circuit	3	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**3**	**1**	**4**
Non-patterned	3	1	
WW Confirmed Malfunctions	**10**	**2**	**12**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN CRT-D

Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158

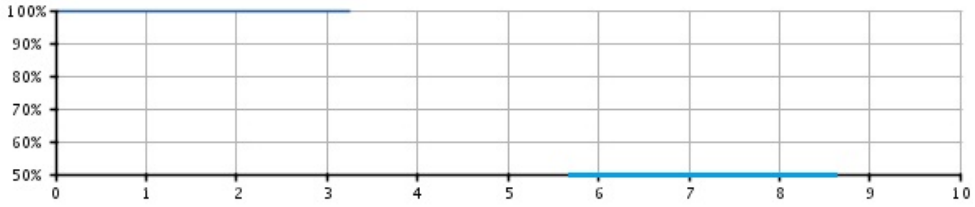
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

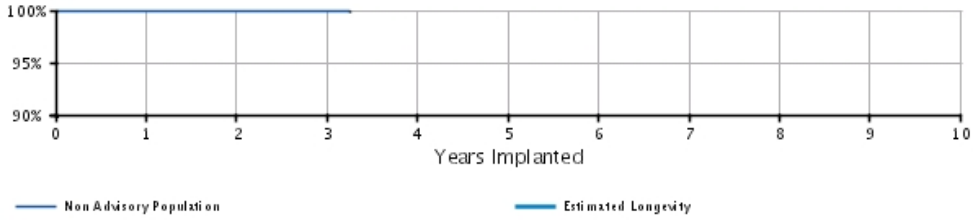
U.S. Registered Implants: 42,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 39,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:15
Without Compromised Therapy:13
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 42000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.2/+0.1)	99.86 @ 39 mo. (-0.2/+0.1)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.93 (-0.1/+0.0)	99.93 @ 39 mo. (-0.1/+0.0)	–	–	–	–	–	–
	Effective Sample Size	23515	9235	1096	274	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN CRT-D

Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

DYNAGEN/INOGEN/ORIGEN CRT-D
Models G050/G051/G056/G058/G140/ G141/G146/G148/G150/G151/ G154/G156/G158

Worldwide Distribution: 64,000
Worldwide Confirmed Malfunctions: 28

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**16**	**3**	**19**
[61] High voltage circuit component	8	-	
[62] Integrated circuit	8	2	
[63] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**5**	**1**	**6**
[48] Memory errors	5	1	
Other	**2**	**1**	**3**
Non-patterned	2	1	
WW Confirmed Malfunctions	**23**	**5**	**28**

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA CRT-D

Models N050/N051/N052/N053/N140/
N141/N142/N143/N160/N161/
N162/N163/N164/N165/P052/
P053/P142/P143/P162/P163/
P165

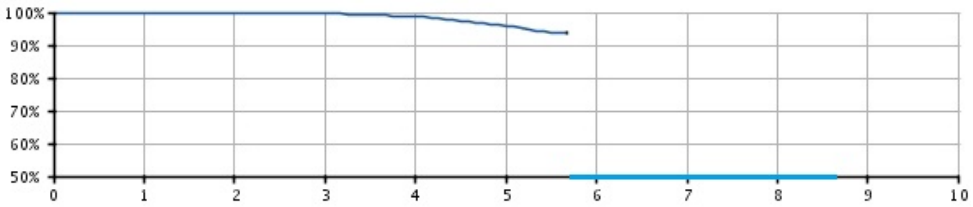
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

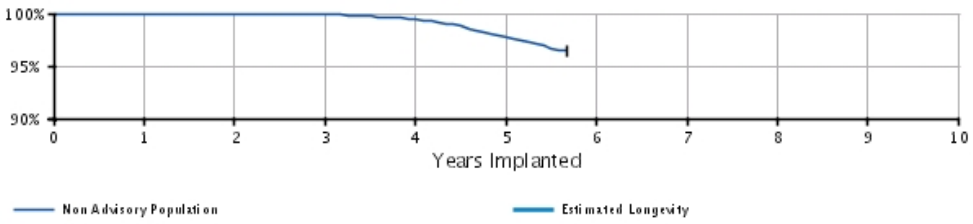
U.S. Registered Implants: 52,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 39,000

U.S. Normal Battery Depletions: 312
U.S. Unconfirmed Reports of Premature Battery Depletion : 53
U.S. Malfunctions:346
Without Compromised Therapy:333
With Compromised Therapy:13

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 52000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.88 (-0.0/+0.0)	99.63 (-0.1/+0.1)	98.62 (-0.2/+0.1)	95.76 (-0.4/+0.4)	93.69 @ 68 mo. (-0.7/+0.7)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.88 (-0.0/+0.0)	99.40 (-0.1/+0.1)	97.68 (-0.3/+0.3)	96.53 @ 68 mo. (-0.6/+0.5)	–	–	–	–
	Effective Sample Size	46473	40235	30789	17099	5390	269	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA CRT-D

Models N050/N051/N052/N053/N140/
N141/N142/N143/N160/N161/
N162/N163/N164/N165/P052/
P053/P142/P143/P162/P163/
P165

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INCEPTA/ENERGEN/PUNCTUA CRT-D
Models N050/N051/N052/N053/N140/ N141/N142/N143/N160/N161/ N162/N163/N164/N165/P052/ P053/P142/P143/P162/P163/ P165

Worldwide Distribution: 81,000
Worldwide Confirmed Malfunctions: 530

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**491**	**11**	**502**
[39] Safety Core-electrocautery	5	1	
[40] High-voltage capacitor	-	3	
[44] Low-voltage capacitors	1	-	
[47] Integrated circuit	1	6	
[50] Battery	3	-	
[51] Low-voltage capacitor	481	1	
Mechanical	**-**	**6**	**6**
[35] Transformer	-	6	
Software	**9**	**-**	**9**
[48] Memory errors	9	-	
Other	**10**	**3**	**13**
Non-patterned	10	3	
WW Confirmed Malfunctions	**510**	**20**	**530**

More details about malfunctions

References cited in table above

COGNIS

Models N106/N107/N108/N118/N119/
N120/P106/P107/P108

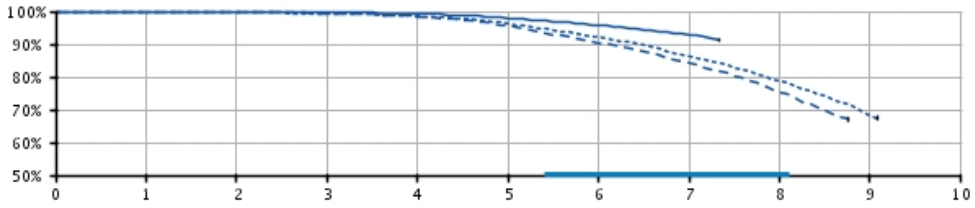
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

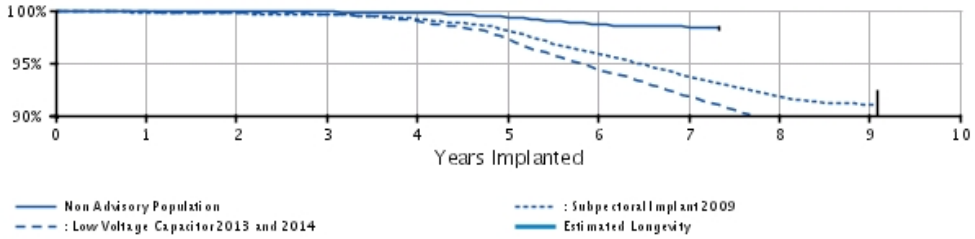
U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 35,000

U.S. Normal Battery Depletions: 3,298
U.S. Unconfirmed Reports of Premature Battery Depletion : 131
U.S. Malfunctions:1751
Without Compromised Therapy:1575
With Compromised Therapy:176

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 36000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.20 (-0.1/+0.1)	97.95 (-0.2/+0.2)	95.76 (-0.3/+0.3)	92.94 (-0.5/+0.5)	91.24 @ 88 mo. (-1.0/+0.9)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.77 (-0.1/+0.1)	99.34 (-0.1/+0.1)	98.66 (-0.2/+0.2)	98.37 (-0.2/+0.2)	98.30 @ 88 mo. (-0.3/+0.2)	–	–
	Effective Sample Size	31502	28110	25049	22234	19340	12965	2737	430	–	–
Subpectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1/+0.0)	99.63 (-0.1/+0.0)	99.37 (-0.1/+0.0)	98.55 (-0.1/+0.0)	96.36 (-0.1/+0.0)	92.07 (-0.1/+0.1)	86.42 (-0.1/+0.1)	78.79 (-0.4/+0.5)	68.50 (-1.6/+1.5)	67.47 @ 109 mo. (-1.6/+1.5)
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.0/+0.1)	99.70 (-0.0/+0.1)	99.61 (-0.1/+0.1)	99.17 (-0.1/+0.1)	98.10 (-0.1/+0.1)	95.82 (-0.2/+0.3)	93.70 (-0.3/+0.3)	91.87 (-0.4/+0.5)	90.99 (-0.4/+0.5)	90.99 @ 109 mo. (-1.6/+1.5) –
	Effective Sample Size	27492	24360	21664	19173	16710	14179	11824	7274	754	401
Low Voltage Capacitor 2013 and 2014*	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.46 (-0.1/+0.1)	98.41 (-0.1/+0.1)	95.54 (-0.1/+0.1)	90.49 (-0.1/+0.1)	84.17 (-0.3/+0.1)	75.47 (-0.3/+0.2)	67.11 @ 105 mo. (-1.4/+1.0)	–

Registered Implants: 26,000											
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.77 (-0.1/+0.1)	99.65 (-0.1/+0.1)	98.96 (-0.1/+0.1)	97.31 (-0.1/+0.1)	94.35 (-0.1/+0.1)	91.81 (-0.3/+0.1)	89.19 (-0.4/+0.2)	87.73 @ 105 mo. (-1.4/+1.0)	–
	Effective Sample Size	22615	20019	17824	15745	13646	11468	9284	3141	253	–

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

COGNIS

Models N106/N107/N108/N118/N119/
N120/P106/P107/P108

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

COGNIS
Models N106/N107/N108/N118/N119/ N120/P106/P107/P108

Worldwide Distribution: 109,000
Worldwide Confirmed Malfunctions: 2323

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1991**	**138**	**2129**
[2] Low Voltage Capacitor 2014 (Advisory issued)	1443	74	
[39] Safety Core-electrocautery	48	21	
[40] High-voltage capacitor	1	6	
[44] Low-voltage capacitors	7	-	
[47] Integrated circuit	8	20	
[49] High voltage circuit	-	1	
[50] Battery	43	6	
[51] Low-voltage capacitor	441	10	
Mechanical	**43**	**93**	**136**
[3] Subpectoral implant 2009 (Advisory issued)	20	50	
[35] Transformer	-	9	
[38] Difficulty securing lead	9	9	
[42] Header contacts	8	8	
[66] Header	6	17	
Software	**15**	**1**	**16**
[43] Safety Core-programming	1	-	
[45] Alert messages not displayed post-EOL	2	-	
[48] Memory errors	12	1	
Other	**34**	**8**	**42**
Non-patterned	34	8	
WW Confirmed Malfunctions	**2083**	**240**	**2323**

More details about malfunctions

References cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

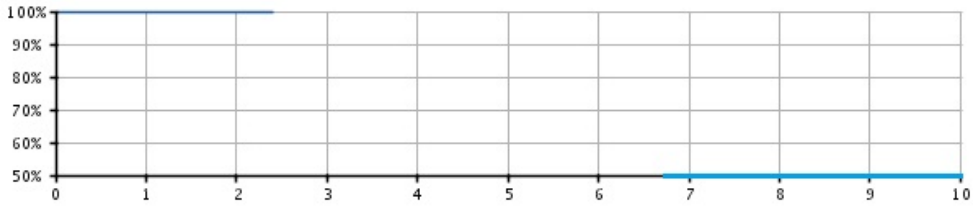
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

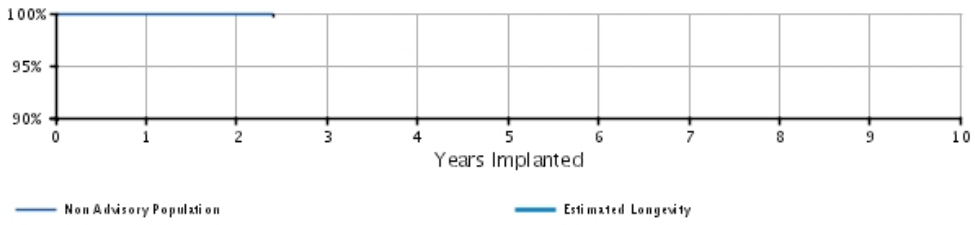
U.S. Registered Implants: 14,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 13,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:7
Without Compromised Therapy:6
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.83 @ 29 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.86 (-0.2/+0.1)	99.86 @ 29 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Effective Sample Size	6277	1316	310	–	–	–	–	–	–	–

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

VISIONIST/VALITUDE Models U125/U128/U225/U226/U228

Worldwide Distribution: 29,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**6**	**1**	**7**
[44] Low-voltage capacitors	1	-	
[62] Integrated circuit	3	1	
[64] Capacitor	2	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**7**	**1**	**8**

More details about malfunctions

References cited in table above

INVIVE

Models V172/V173/V182/V183/W172/
W173

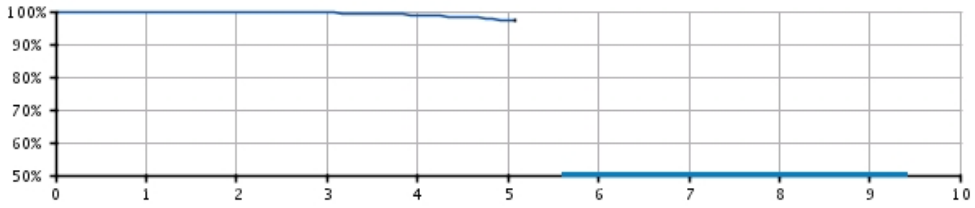
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

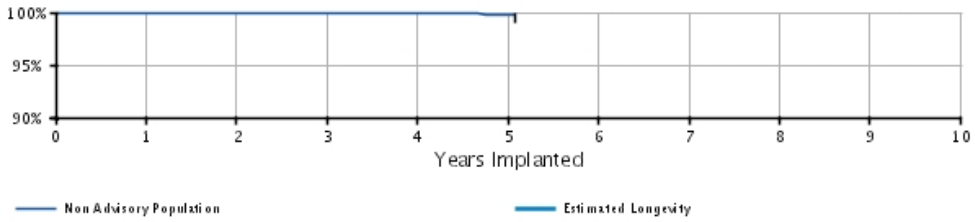
U.S. Registered Implants: 8,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 58
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:2
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.51 (-0.2/+0.2)	98.94 (-0.4/+0.3)	97.30 (-1.1/+0.8)	97.30 @ 61 mo. (-1.1/+0.8)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.84 (-0.8/+0.1)	99.84 @ 61 mo. (-0.8/+0.1)	–	–	–	–
	Effective Sample Size	6747	5764	4377	2148	376	283	–	–	–	–

INVIVE

Models V172/V173/V182/V183/W172/
W173

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INVIVE
Models V172/V173/V182/V183/W172/ W173

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[44] Low-voltage capacitors	-	1	
Mechanical	**-**	**-**	**0**
Software	**3**	**-**	**3**
[48] Memory errors	3	-	
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**3**	**1**	**4**

More details about malfunctions

References cited in table above

INTUA

Models V272/V273/V282/V283/W272/
W273

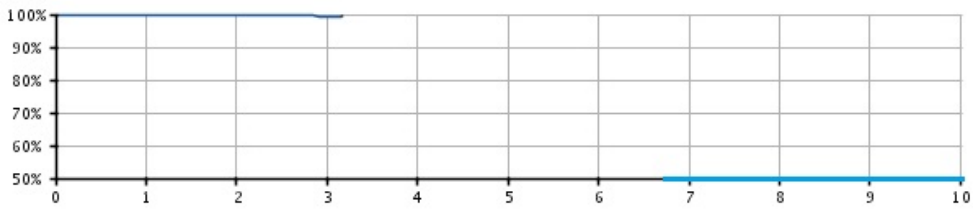
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

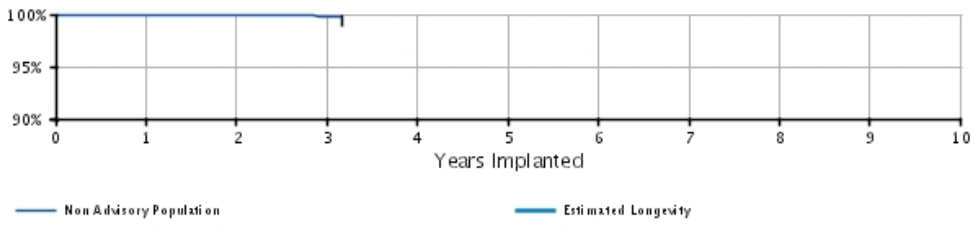
U.S. Registered Implants: 3,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 8
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.3/+0.1)	99.66 (-0.4/+0.2)	99.41 (-0.7/+0.3)	99.41 @ 38 mo. (-0.7/+0.3)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.96 (-0.3/+0.0)	99.77 (-1.0/+0.2)	99.77 @ 38 mo. (-1.0/+0.2)	–	–	–	–	–	–
	Effective Sample Size	2200	1606	423	246	–	–	–	–	–	–

INTUA

Models V272/V273/V282/V283/W272/
W273

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INTUA
Models V272/V273/V282/V283/W272/ W273

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR 2

Models H140/H145

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

CONTAK RENEWAL TR 2 Models H140/H145

Worldwide Distribution: 31,000
Worldwide Confirmed Malfunctions: 31

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[12] Capacitor	1	-	
Mechanical	**4**	**-**	**4**
[16] Seal plug	1	-	
[22] Setscrew block	2	-	
[30] Seal plug	1	-	
Software	**14**	**-**	**14**
[20] Memory error	1	-	
[25] Stored EGMs	13	-	
Other	**11**	**1**	**12**
Non-patterned	10	1	
[28] Alert messages	1	-	
WW Confirmed Malfunctions	**30**	**1**	**31**

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR

Models H120/H125

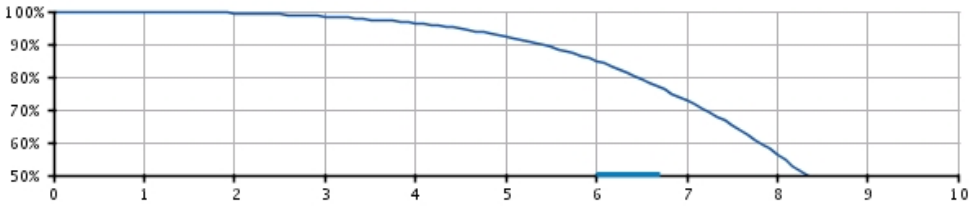
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

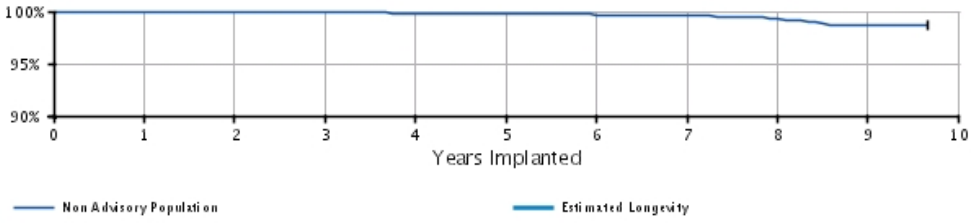
U.S. Registered Implants: 19,000
U.S. Approval Date: January 2004
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 3,230
U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Malfunctions:54
Without Compromised Therapy:52
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 19000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.47 (-0.2/+0.2)	96.35 (-0.4/+0.3)	92.36 (-0.5/+0.5)	84.94 (-0.8/+0.7)	72.76 (-1.1/+1.0)	56.15 (-1.5/+1.4)	38.45 (-1.8/+1.9)	28.18 @ 116 mo. (-2.1/+2.2)
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.77 (-0.1/+0.1)	99.68 (-0.1/+0.1)	99.60 (-0.2/+0.1)	99.27 (-0.3/+0.2)	98.73 (-0.6/+0.4)	98.73 @ 116 mo. (-0.6/+0.4)
	Effective Sample Size	15565	13554	11811	10232	8581	6088	3424	1582	559	219
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

CONTAK RENEWAL TR

Models H120/H125

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

CONTAK RENEWAL TR Models H120/H125

Worldwide Distribution: 19,000
Worldwide Confirmed Malfunctions: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[5] Low-voltage capacitor (Advisory issued)	1	-	
[12] Capacitor	-	1	
Mechanical	**5**	**-**	**5**
[16] Seal plug	5	-	
Software	**29**	**-**	**29**
[25] Stored EGMs	29	-	
Other	**17**	**1**	**18**
Non-patterned	11	1	
[28] Alert messages	5	-	
[41] Magnet rate	1	-	
WW Confirmed Malfunctions	**52**	**2**	**54**

More details about malfunctions

References cited in table above

EMBLEM S-ICD

Models A209/A219

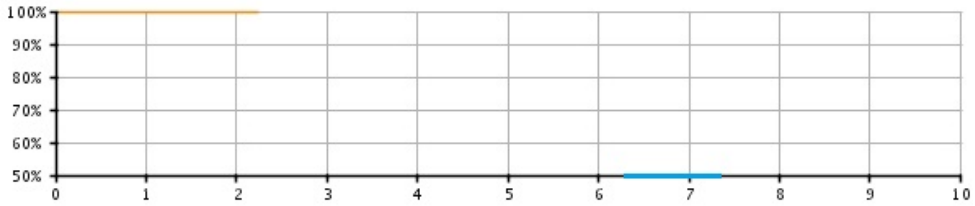
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

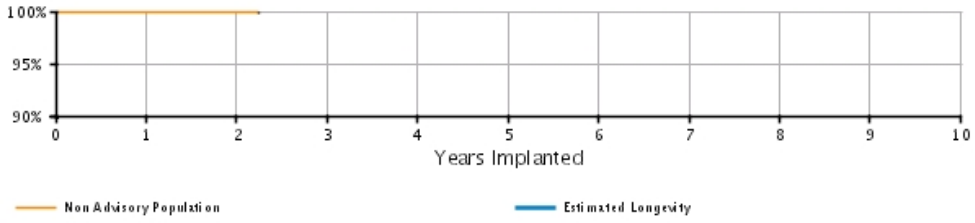
U.S. Registered Implants: 14,000
U.S. Approval Date: March 2015
U.S. Estimated Active Implants: 13,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:6
Without Compromised Therapy:2
With Compromised Therapy:4

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.91 @ 27 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.93 @ 27 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	7127	1385	292	–	–	–	–	–	–	–

EMBLEM S-ICD

Models A209/A219

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

EMBLEM S-ICD Models A209/A219

Worldwide Distribution: 28,000
Worldwide Confirmed Malfunctions: 13

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**-**	**0**
Software	**-**	**1**	**1**
[1] Memory corruption (Advisory issued)	-	1	
Other	**6**	**6**	**12**
Non-patterned	5	2	
[54] Telemetry	1	4	
WW Confirmed Malfunctions	**6**	**7**	**13**

More details about malfunctions

References cited in table above

AUTOGEN ICD EL DR

Models D162/D163/D176/D177

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

AUTOGEN ICD EL DR Models D162/D163/D176/D177

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**1**	**3**
[61] High voltage circuit component	1	-	
[62] Integrated circuit	-	1	
[63] High voltage capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	1	
WW Confirmed Malfunctions	**3**	**2**	**5**

More details about malfunctions

References cited in table above

AUTOGEN ICD EL VR

Models D160/D161/D174/D175

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

AUTOGEN ICD EL VR Models D160/D161/D174/D175

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	1	1	2
[48] Memory errors	1	1	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL DR

Models D052/D053/D142/D143/D152/
D153

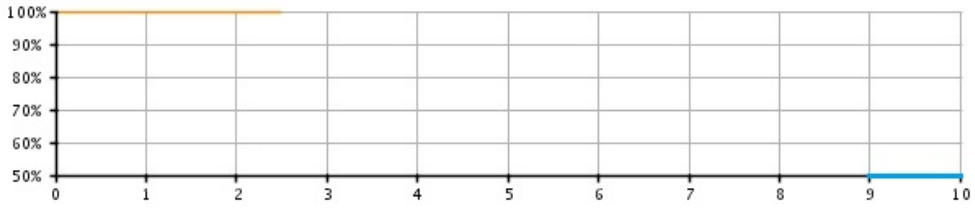
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

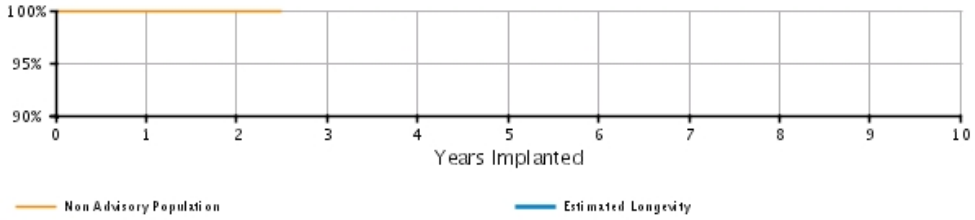
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 21,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:3
Without Compromised Therapy:2
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.93 (-0.1/+0.0)	99.93 @ 30 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 @ 30 mo. (-0.0/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	10755	3045	306	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD EL DR

Models D052/D053/D142/D143/D152/
D153

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

DYNAGEN/INOGEN/ORIGEN ICD EL DR Models D052/D053/D142/D143/D152/ D153

Worldwide Distribution: 31,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**1**	**5**
[44] Low-voltage capacitors	1	-	
[61] High voltage circuit component	3	-	
[62] Integrated circuit	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**5**	**1**	**6**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL VR

Models D050/D051/D140/D141/D150/
D151

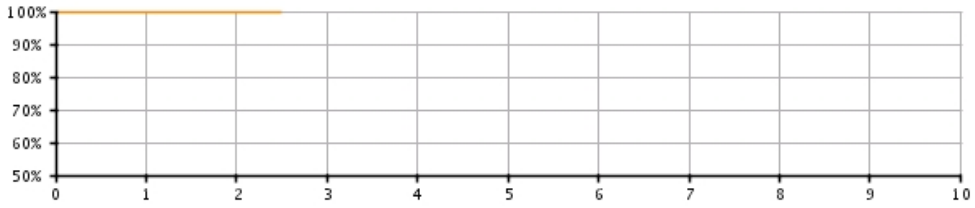
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

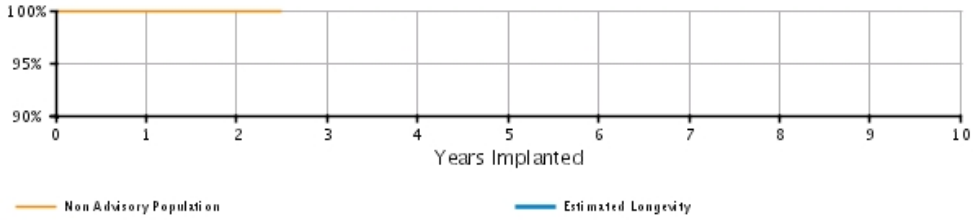
U.S. Registered Implants: 20,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 19,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:3
Without Compromised Therapy:3
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 20000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.91 @ 30 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 30 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	10419	2977	293	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD EL VR

Models D050/D051/D140/D141/D150/
D151

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

DYNAGEN/INOGEN/ORIGEN ICD EL VR Models D050/D051/D140/D141/D150/ D151

Worldwide Distribution: 32,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[61] High voltage circuit component	1	-	
Mechanical	**-**	**-**	**0**
Software	**2**	**-**	**2**
[48] Memory errors	2	-	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**5**	**0**	**5**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

Models D002/D003/D012/D013/D022/
D023

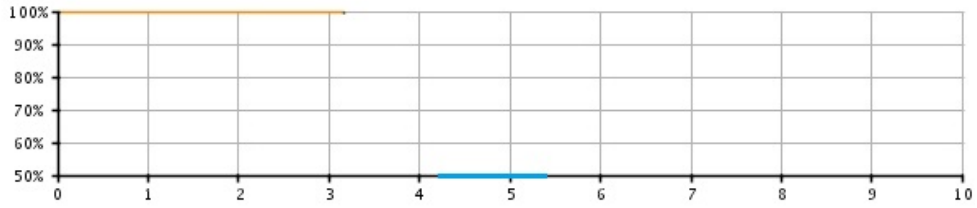
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

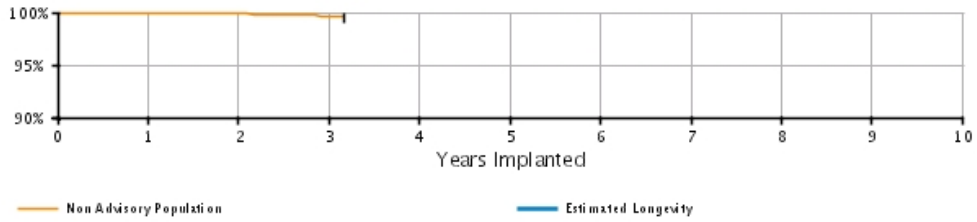
U.S. Registered Implants: 6,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:7
Without Compromised Therapy:6
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.58 (-0.5/+0.2)	99.58 @ 38 mo. (-0.5/+0.2)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.89 (-0.2/+0.1)	99.65 (-0.6/+0.2)	99.65 @ 38 mo. (-0.6/+0.2)	–	–	–	–	–	–
	Effective Sample Size	4369	2388	524	281	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

Models D002/D003/D012/D013/D022/
D023

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

DYNAGEN/INOGEN/ORIGEN ICD MINI DR Models D002/D003/D012/D013/D022/ D023

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**6**	**1**	**7**
[61] High voltage circuit component	6	-	
[63] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**2**	**1**	**3**
Non-patterned	2	1	
WW Confirmed Malfunctions	**8**	**2**	**10**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

Models D000/D001/D010/D011/D020/
D021

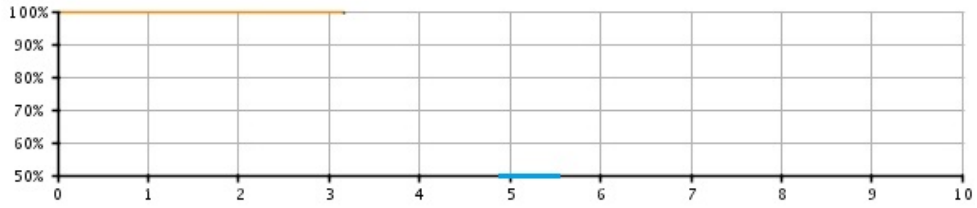
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

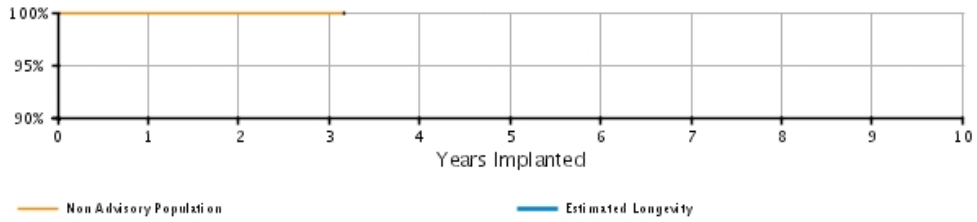
U.S. Registered Implants: 6,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 3
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:4
Without Compromised Therapy:3
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.72 (-0.6/+0.2)	99.72 @ 38 mo. (-0.6/+0.2)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.91 @ 38 mo. (-0.2/+0.1)	–	–	–	–	–	–
	Effective Sample Size	4339	2351	441	214	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

Models D000/D001/D010/D011/D020/
D021

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

DYNAGEN/INOGEN/ORIGEN ICD MINI VR Models D000/D001/D010/D011/D020/ D021

Worldwide Distribution: 15,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**1**	**6**
[44] Low-voltage capacitors	2	-	
[61] High voltage circuit component	3	-	
[63] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**1**	**1**	**2**
[48] Memory errors	1	1	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**8**	**2**	**10**

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA ICD DR

Models E052/E053/E142/E143/E162/
E163/F052/F053/F142/F143/
F162/F163

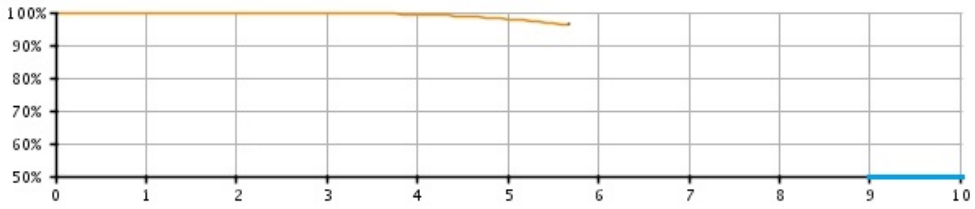
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

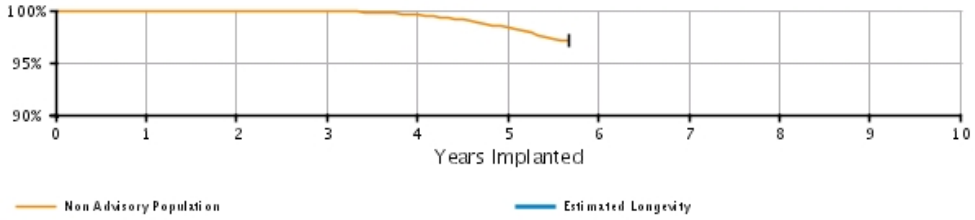
U.S. Registered Implants: 47,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 38,000

U.S. Normal Battery Depletions: 52
U.S. Unconfirmed Reports of Premature Battery Depletion : 22
U.S. Malfunctions:214
Without Compromised Therapy:206
With Compromised Therapy:8

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 47000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.81 (-0.1/+0.0)	99.39 (-0.1/+0.1)	97.98 (-0.3/+0.3)	96.47 @ 68 mo. (-0.7/+0.6)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.58 (-0.1/+0.1)	98.38 (-0.3/+0.2)	97.14 @ 68 mo. (-0.7/+0.6)	–	–	–	–
	Effective Sample Size	41307	35524	25915	14109	4315	238	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA ICD DR

Models E052/E053/E142/E143/E162/
E163/F052/F053/F142/F143/
F162/F163

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INCEPTA/ENERGEN/PUNCTUA ICD DR Models E052/E053/E142/E143/E162/ E163/F052/F053/F142/F143/ F162/F163

Worldwide Distribution: 72,000
Worldwide Confirmed Malfunctions: 328

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**301**	**7**	**308**
[40] High-voltage capacitor	1	2	
[44] Low-voltage capacitors	3	-	
[47] Integrated circuit	6	3	
[50] Battery	13	1	
[51] Low-voltage capacitor	277	1	
[57] High voltage circuit	1	-	
Mechanical	**-**	**2**	**2**
[35] Transformer	-	2	
Software	**3**	**-**	**3**
[48] Memory errors	3	-	
Other	**10**	**5**	**15**
Non-patterned	10	5	
WW Confirmed Malfunctions	**314**	**14**	**328**

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA ICD VR

Models E050/E051/E140/E141/E160/
E161/F050/F051/F140/F141/
F160/F161

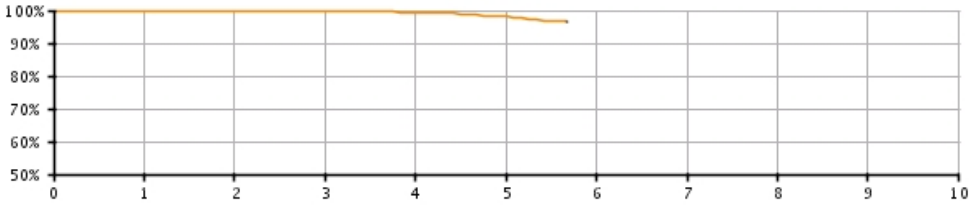
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

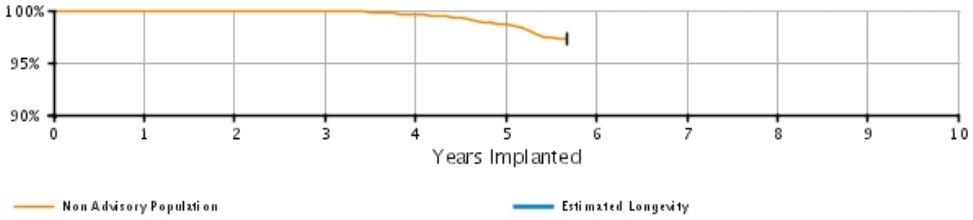
U.S. Registered Implants: 39,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 32,000

U.S. Normal Battery Depletions: 57
U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Malfunctions:159
Without Compromised Therapy:144
With Compromised Therapy:15

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 39000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.78 (-0.1/+0.0)	99.35 (-0.1/+0.1)	98.09 (-0.3/+0.3)	96.53 @ 68 mo. (-0.8/+0.6)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.58 (-0.1/+0.1)	98.63 (-0.3/+0.2)	97.30 @ 68 mo. (-0.7/+0.6)	–	–	–	–
	Effective Sample Size	34796	29861	21541	11466	3621	210	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA ICD VR

Models E050/E051/E140/E141/E160/
E161/F050/F051/F140/F141/
F160/F161

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INCEPTA/ENERGEN/PUNCTUA ICD VR Models E050/E051/E140/E141/E160/ E161/F050/F051/F140/F141/ F160/F161

Worldwide Distribution: 68,000
Worldwide Confirmed Malfunctions: 244

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**210**	**10**	**220**
[40] High-voltage capacitor	1	2	
[47] Integrated circuit	2	5	
[50] Battery	15	1	
[51] Low-voltage capacitor	192	1	
[57] High voltage circuit	-	1	
Mechanical	**-**	**6**	**6**
[35] Transformer	-	6	
Software	**5**	**-**	**5**
[48] Memory errors	5	-	
Other	**7**	**6**	**13**
Non-patterned	7	6	
WW Confirmed Malfunctions	**222**	**22**	**244**

More details about malfunctions

References cited in table above

SQ-RX S-ICD

Model 1010

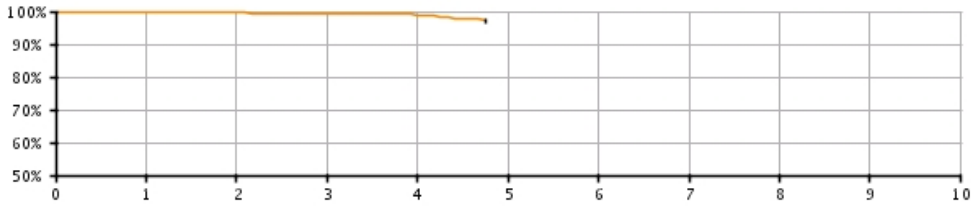
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

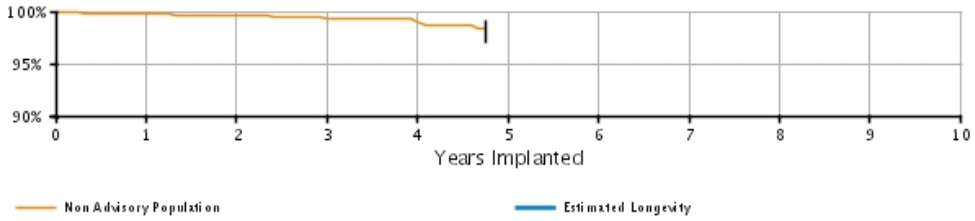
U.S. Registered Implants: 8,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 138
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:46
Without Compromised Therapy:16
With Compromised Therapy:30

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.75 (-0.1/+0.1)	99.51 (-0.2/+0.1)	99.25 (-0.3/+0.2)	98.80 (-0.8/+0.5)	97.16 @ 57 mo. (-2.0/+1.2)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.77 (-0.1/+0.1)	99.55 (-0.2/+0.1)	99.36 (-0.3/+0.2)	99.00 (-0.8/+0.4)	98.39 @ 57 mo. (-1.4/+0.8)	–	–	–	–	–
	Effective Sample Size	6541	5666	2714	421	238	–	–	–	–	–

SQ-RX S-ICD

Model 1010

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

SQ-RX S-ICD Model 1010

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 116

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**8**	**3**	**11**
[55] Unintended Fuse Activation 2013	-	3	
[60] Charge Timeout Alert	8	-	
Mechanical	**16**	**26**	**42**
[52] High cathode condition	1	2	
[53] Battery depletion	15	24	
Software	**3**	**-**	**3**
[56] Unintended Battery Depletion Alert	3	-	
Other	**19**	**41**	**60**
Non-patterned	16	32	
[54] Telemetry	3	9	
WW Confirmed Malfunctions	**46**	**70**	**116**

More details about malfunctions

References cited in table above

TELIGEN DR

Models E110/E111/F110/F111

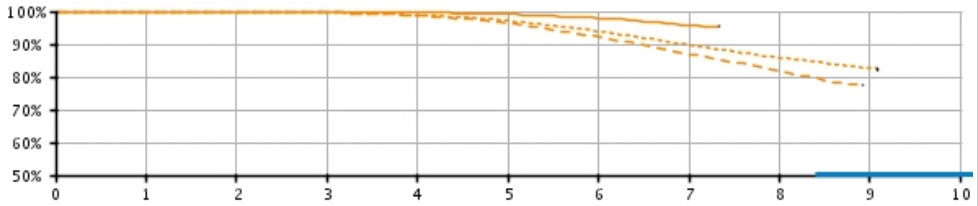
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

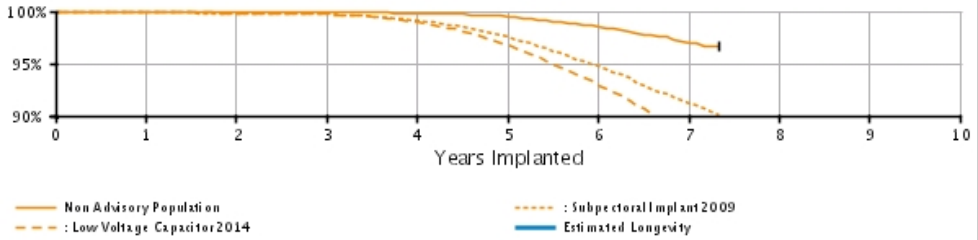
U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 37,000

U.S. Normal Battery Depletions: 442
U.S. Unconfirmed Reports of Premature Battery Depletion : 174
U.S. Malfunctions:2159
Without Compromised Therapy:2026
With Compromised Therapy:133

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 30000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.86 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.17 (-0.1/+0.1)	97.98 (-0.2/+0.2)	95.77 (-0.5/+0.4)	95.47 @ 88 mo. (-0.6/+0.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.48 (-0.1/+0.1)	98.52 (-0.2/+0.2)	96.92 (-0.4/+0.4)	96.66 @ 88 mo. (-0.5/+0.4)	–	–
	Effective Sample Size	26439	23336	20589	18090	15811	10942	2681	486	–	–
Subpectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.61 (-0.1/+0.1)	98.88 (-0.1/+0.1)	97.17 (-0.1/+0.1)	93.93 (-0.1/+0.1)	89.77 (-0.2/+0.1)	85.90 (-0.2/+0.3)	82.69 (-1.2/+0.5)	82.51 @ 109 mo. (-1.2/+0.5)
	Malfunctions Only(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.12 (-0.1/+0.1)	97.56 (-0.1/+0.1)	94.69 (-0.1/+0.1)	91.20 (-0.2/+0.3)	88.51 (-0.2/+0.3)	87.53 (-0.4/+0.3)	87.53 @ 109 mo. (-0.4/+0.3) –
	Effective Sample Size	26747	23499	20669	18050	15605	13219	11046	7230	881	473
Low Voltage Capacitor 2014* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.58 (-0.1/+0.1)	98.73 (-0.1/+0.1)	96.36 (-0.1/+0.1)	92.11 (-0.1/+0.1)	86.91 (-0.1/+0.2)	81.71 (-0.3/+0.3)	77.62 @ 107 mo. (-0.4/+0.3)	–

23,000											
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.82 (-0.1/+0.1)	99.69 (-0.1/+0.1)	98.95 (-0.1/+0.1)	96.76 (-0.1/+0.1)	92.93 (-0.1/+0.1)	88.45 (-0.1/+0.1)	84.64 (-0.2/+0.1)	82.65 @ 107 mo. (-0.4/+0.3)	–
	Effective Sample Size	20715	18217	16008	13972	11984	10028	8208	3239	202	–

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

TELIGEN DR

Models E110/E111/F110/F111

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

TELIGEN DR
Models E110/E111/F110/F111

Worldwide Distribution: 91,000
Worldwide Confirmed Malfunctions: 2822

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2588**	**102**	**2690**
[2] Low Voltage Capacitor 2014 (Advisory issued)	1906	45	
[39] Safety Core-electrocautery	3	-	
[40] High-voltage capacitor	1	7	
[44] Low-voltage capacitors	7	-	
[47] Integrated circuit	20	20	
[50] Battery	194	25	
[51] Low-voltage capacitor	457	5	
Mechanical	**20**	**54**	**74**
[3] Subpectoral implant 2009 (Advisory issued)	3	12	
[35] Transformer	-	20	
[37] Seal plug	3	-	
[38] Difficulty securing lead	9	8	
[42] Header contacts	3	11	
[66] Header	2	3	
Software	**18**	**-**	**18**
[45] Alert messages not displayed post-EOL	3	-	
[48] Memory errors	15	-	
Other	**29**	**11**	**40**
Non-patterned	29	11	
WW Confirmed Malfunctions	**2655**	**167**	**2822**

More details about malfunctions

References cited in table above

TELIGEN VR

Models E102/E103/F102/F103

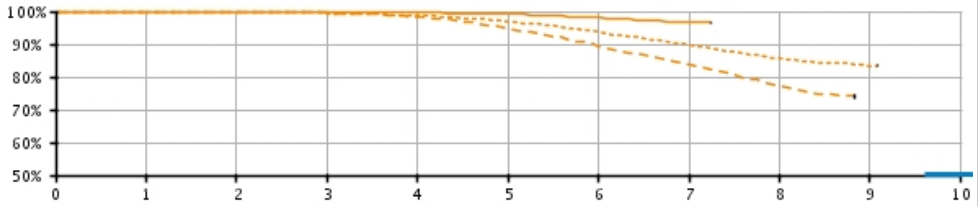
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

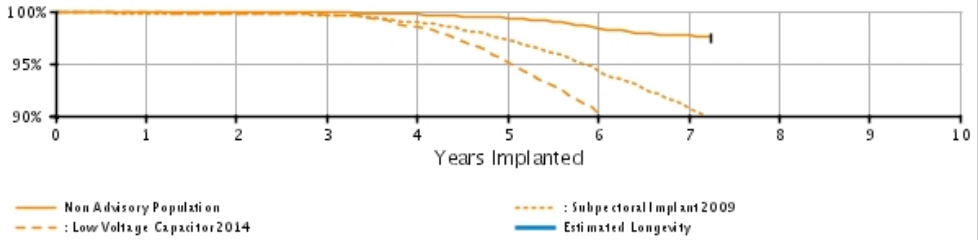
U.S. Registered Implants: 38,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 21,000

U.S. Normal Battery Depletions: 104
U.S. Unconfirmed Reports of Premature Battery Depletion : 127
U.S. Malfunctions:1450
Without Compromised Therapy:1350
With Compromised Therapy:100

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 18000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.13 (-0.2/+0.2)	98.03 (-0.3/+0.3)	96.77 (-0.5/+0.5)	96.64 @ 87 mo. (-0.6/+0.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.69 (-0.1/+0.1)	99.35 (-0.2/+0.1)	98.41 (-0.3/+0.2)	97.66 (-0.4/+0.4)	97.53 @ 87 mo. (-0.5/+0.4)	–	–
	Effective Sample Size	16275	14325	12583	11032	9634	6223	1036	307	–	–
Subpectoral Implant 2009* Registered Implants: 16,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.0/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.1/+0.1)	96.93 (-0.1/+0.1)	93.68 (-0.1/+0.1)	89.64 (-0.1/+0.1)	85.70 (-0.2/+0.1)	83.49 (-0.6/+0.5)	83.49 @ 109 mo. (-0.6/+0.5)
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.63 (-0.1/+0.1)	98.93 (-0.1/+0.1)	97.31 (-0.1/+0.1)	94.36 (-0.1/+0.2)	90.67 (-0.4/+0.3)	87.29 (-0.5/+0.6)	85.61 (-0.6/+0.9)	85.61 @ 109 mo. (-0.6/+0.5)
	Effective Sample Size	13679	11992	10511	9146	7859	6658	5551	3626	473	259
Low Voltage Capacitor 2014* Registered Implants: 12,000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.72 (-0.0/+0.1)	99.51 (-0.0/+0.1)	98.23 (-0.1/+0.1)	94.78 (-0.2/+0.1)	89.46 (-0.3/+0.2)	83.58 (-0.4/+0.2)	77.38 (-0.5/+0.6)	74.17 @ 106 mo. (-1.5/+1.6)	–
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.64 (-0.1/+0.1)	98.45 (-0.1/+0.1)	95.14 (-0.1/+0.1)	90.24 (-0.1/+0.1)	84.88 (-0.3/+0.2)	79.51 (-0.5/+0.6)	77.01 @ 106 mo.	–

									(-1.5/+1.6)	
	Effective Sample Size	10903	9576	8399	7286	6164	5086	3996	1467	203	–

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

TELIGEN VR

Models E102/E103/F102/F103

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

TELIGEN VR
Models E102/E103/F102/F103

Worldwide Distribution: 66,000
Worldwide Confirmed Malfunctions: 2309

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2093**	**83**	**2176**
[2] Low Voltage Capacitor 2014 (Advisory issued)	1513	34	
[39] Safety Core-electrocautery	1	1	
[40] High-voltage capacitor	-	3	
[44] Low-voltage capacitors	5	-	
[47] Integrated circuit	11	15	
[50] Battery	285	30	
[51] Low-voltage capacitor	278	-	
Mechanical	**24**	**71**	**95**
[3] Subpectoral implant 2009 (Advisory issued)	7	18	
[21] Transformer	-	2	
[35] Transformer	-	14	
[37] Seal plug	1	-	
[38] Difficulty securing lead	-	10	
[42] Header contacts	14	19	
[66] Header	2	8	
Software	**16**	**-**	**16**
[4] Respiratory Sensor Oversensing	1	-	
[45] Alert messages not displayed post-EOL	4	-	
[48] Memory errors	11	-	
Other	**11**	**11**	**22**
Non-patterned	11	11	
WW Confirmed Malfunctions	**2144**	**165**	**2309**

More details about malfunctions

References cited in table above

CONFIENT DR

Models E030/F030

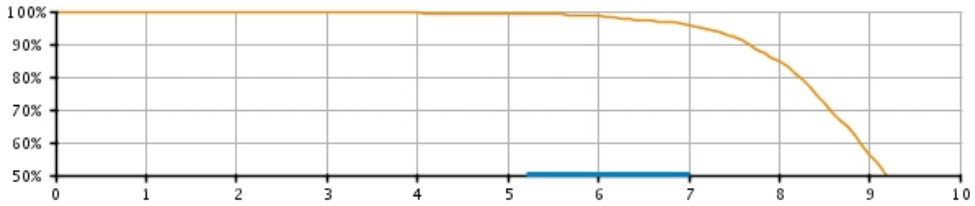
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

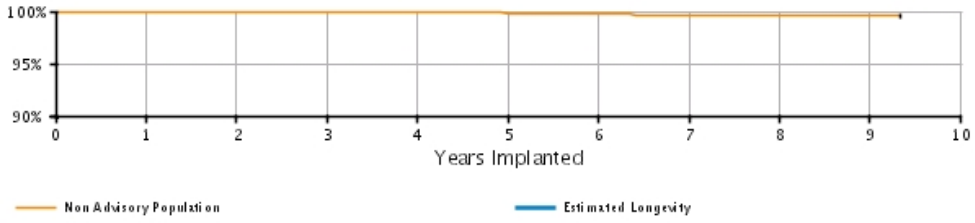
U.S. Registered Implants: 7,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 970
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:14
Without Compromised Therapy:11
With Compromised Therapy:3

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.87 (-0.1/+0.1)	99.71 (-0.2/+0.1)	99.53 (-0.2/+0.2)	99.32 (-0.3/+0.2)	98.54 (-0.4/+0.3)	95.56 (-0.8/+0.7)	84.75 (-1.5/+1.4)	56.15 (-2.4/+2.4)	41.58 @ 112 mo. (-2.9/+2.9)
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.84 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.64 (-0.3/+0.2)	99.60 (-0.3/+0.2)	99.60 (-0.3/+0.2)	99.60 @ 112 mo. (-0.3/+0.2)
	Effective Sample Size	6162	5395	4698	4114	3604	3102	2512	1729	692	263

CONFIENT DR

Models E030/F030

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

CONFIENT DR Models E030/F030

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 14

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**10**	**-**	**10**
[12] Capacitor	1	-	
[14] Integrated circuit	2	-	
[51] Low-voltage capacitor	7	-	
Mechanical	**-**	**1**	**1**
[35] Transformer	-	1	
Software	**-**	**-**	**0**
Other	**1**	**2**	**3**
Non-patterned	1	1	
[19] Battery depletion	-	1	
WW Confirmed Malfunctions	**11**	**3**	**14**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR

Models L101/L111/L201/L211/L301/
L311

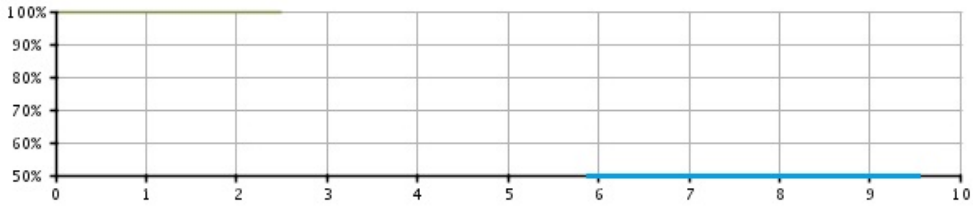
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

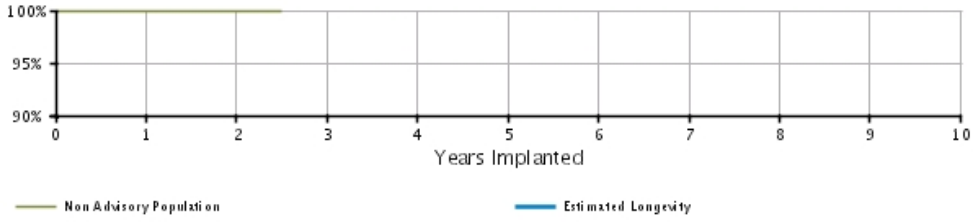
U.S. Registered Implants: 89,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 85,000

U.S. Normal Battery Depletions: 17
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:26
Without Compromised Therapy:21
With Compromised Therapy:5

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 89000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.91 @ 30 mo. (-0.0/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.95 @ 30 mo. (-0.0/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	44744	10634	445	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO DR

Models L101/L111/L201/L211/L301/
L311

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACCOLADE/PROPONENT/ESSENTIO DR Models L101/L111/L201/L211/L301/ L311

Worldwide Distribution: 169,000
Worldwide Confirmed Malfunctions: 40

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**23**	**4**	**27**
[44] Low-voltage capacitors	2	-	
[62] Integrated circuit	9	3	
[64] Capacitor	6	-	
[65] Telemetry	6	1	
Mechanical	**-**	**-**	**0**
Software	**3**	**-**	**3**
[48] Memory errors	3	-	
Other	**7**	**3**	**10**
Non-patterned	7	3	
WW Confirmed Malfunctions	**33**	**7**	**40**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR EL

Models L121/L131/L221/L231/L321/
L331

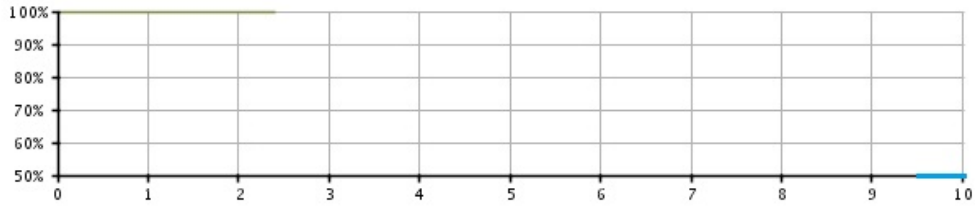
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

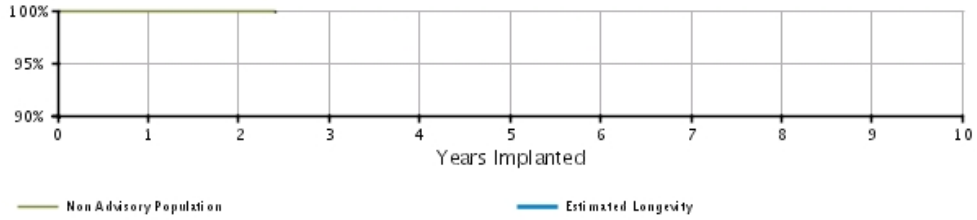
U.S. Registered Implants: 34,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 33,000

U.S. Normal Battery Depletions: 6
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:10
Without Compromised Therapy:10
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 34000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.84 (-0.1/+0.1)	99.84 @ 29 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.93 (-0.1/+0.0)	99.93 @ 29 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	14853	3070	407	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO DR EL

Models L121/L131/L221/L231/L321/
L331

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACCOLADE/PROPONENT/ESSENTIO DR EL
Models L121/L131/L221/L231/L321/ L331

Worldwide Distribution: 82,000
Worldwide Confirmed Malfunctions: 25

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**17**	**-**	**17**
[44] Low-voltage capacitors	1	-	
[62] Integrated circuit	3	-	
[64] Capacitor	10	-	
[65] Telemetry	3	-	
Mechanical	**-**	**-**	**0**
Software	**6**	**-**	**6**
[48] Memory errors	6	-	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**25**	**0**	**25**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO SR

Models L100/L110/L200/L210/L300/
L310

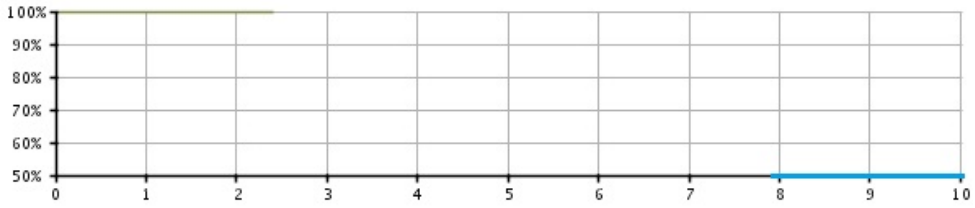
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

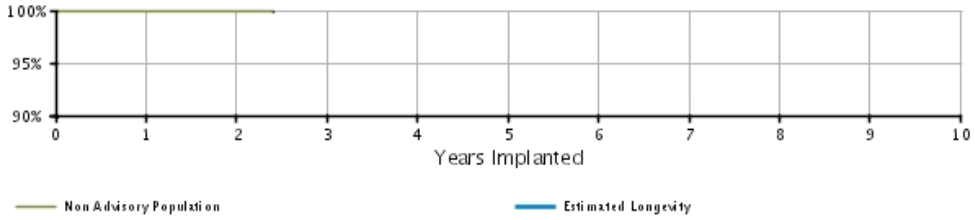
U.S. Registered Implants: 18,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 16,000

U.S. Normal Battery Depletions: 5
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:5
Without Compromised Therapy:4
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 18000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.85 (-0.1/+0.1)	99.85 @ 29 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.94 @ 29 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	8617	1778	216	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO SR

Models L100/L110/L200/L210/L300/
L310

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACCOLADE/PROPONENT/ESSENTIO SR Models L100/L110/L200/L210/L300/ L310

Worldwide Distribution: 59,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**2**	**7**
[44] Low-voltage capacitors	2	-	
[62] Integrated circuit	1	2	
[64] Capacitor	1	-	
[65] Telemetry	1	-	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[48] Memory errors	1	-	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**8**	**2**	**10**

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO/FORMIO DR

Models J063/J066/J173/J176/J273/
J276/J278/J279/K063/K066/
K083/K086/K173/K176/K183/
K186/K273/K276/K278/K279/
K283/K286/K288/K289

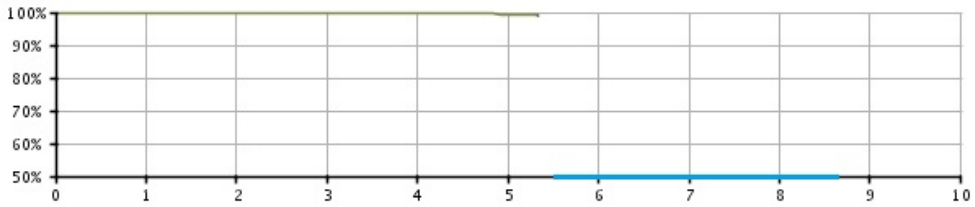
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

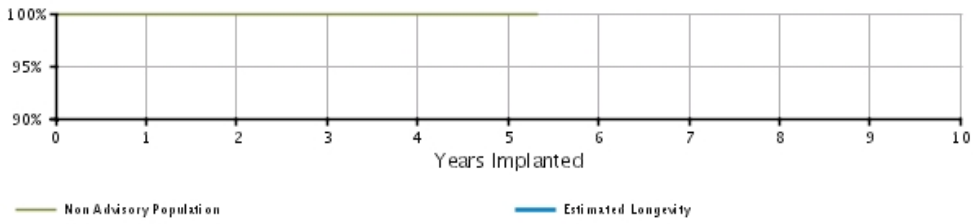
U.S. Registered Implants: 121,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 100,000

U.S. Normal Battery Depletions: 191
U.S. Unconfirmed Reports of Premature Battery Depletion : 15
U.S. Malfunctions:42
Without Compromised Therapy:30
With Compromised Therapy:12

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 121000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.85 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.39 (-0.1/+0.1)	99.14 @ 64 mo. (-0.4/+0.3)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.94 @ 64 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	107666	95186	66232	31499	5478	404	–	–	–	–

ADVANTIO/INGENIO/VITALIO/FORMIO DR

Models J063/J066/J173/J176/J273/
J276/J278/J279/K063/K066/
K083/K086/K173/K176/K183/
K186/K273/K276/K278/K279/
K283/K286/K288/K289

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ADVANTIO/INGENIO/VITALIO/FORMIO DR
Models J063/J066/J173/J176/J273/ J276/J278/J279/K063/K066/ K083/K086/K173/K176/K183/ K186/K273/K276/K278/K279/ K283/K286/K288/K289

Worldwide Distribution: 217,000
Worldwide Confirmed Malfunctions: 63

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**9**	**9**	**18**
[44] Low-voltage capacitors	6	-	
[47] Integrated circuit	3	7	
[59] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**17**	**1**	**18**
[48] Memory errors	17	1	
Other	**22**	**5**	**27**
Non-patterned	22	5	
WW Confirmed Malfunctions	**48**	**15**	**63**

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO EL DR

Models J064/J067/J174/J177/J274/
J277/K064/K067/K084/K087/
K174/K177/K184/K187/K274/
K277/K284/K287

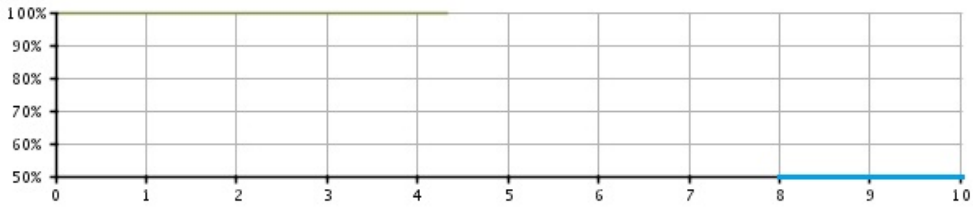
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

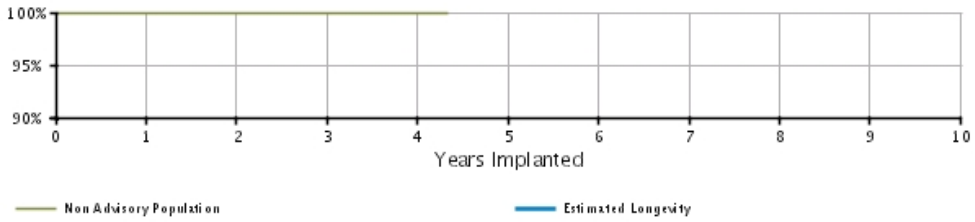
U.S. Registered Implants: 11,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:4
Without Compromised Therapy:3
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.90 (-0.1/+0.1)	99.90 @ 52 mo. (-0.1/+0.1)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 52 mo. (-0.1/+0.0)	–	–	–	–	–
	Effective Sample Size	9683	8224	4293	698	204	–	–	–	–	–

ADVANTIO/INGENIO/VITALIO EL DR

Models J064/J067/J174/J177/J274/
J277/K064/K067/K084/K087/
K174/K177/K184/K187/K274/
K277/K284/K287

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ADVANTIO/INGENIO/VITALIO EL DR
Models J064/J067/J174/J177/J274/ J277/K064/K067/K084/K087/ K174/K177/K184/K187/K274/ K277/K284/K287

Worldwide Distribution: 72,000
Worldwide Confirmed Malfunctions: 29

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[44] Low-voltage capacitors	4	1	
[47] Integrated circuit	-	2	
[59] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**5**	**-**	**5**
[48] Memory errors	4	-	
[58] Respiratory sensor	1	-	
Other	**13**	**2**	**15**
Non-patterned	13	2	
WW Confirmed Malfunctions	**22**	**7**	**29**

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO SR

Models J062/J065/J172/J175/J272/
J275/K062/K065/K082/K085/
K172/K175/K182/K185/K272/
K275/K282/K285

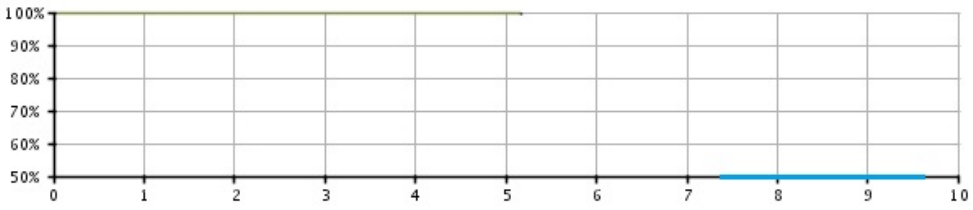
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

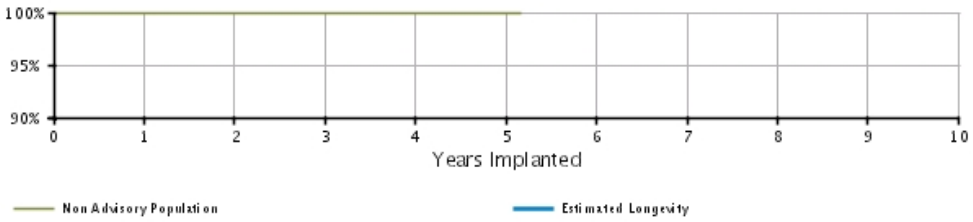
U.S. Registered Implants: 27,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 20,000

U.S. Normal Battery Depletions: 22
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:8
Without Compromised Therapy:7
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 27000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.88 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.71 (-0.3/+0.2)	99.55 @ 62 mo. (-0.6/+0.3)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 @ 62 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	23016	19712	13038	5917	925	370	–	–	–	–

ADVANTIO/INGENIO/VITALIO SR

Models J062/J065/J172/J175/J272/
J275/K062/K065/K082/K085/
K172/K175/K182/K185/K272/
K275/K282/K285

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ADVANTIO/INGENIO/VITALIO SR
Models J062/J065/J172/J175/J272/ J275/K062/K065/K082/K085/ K172/K175/K182/K185/K272/ K275/K282/K285

Worldwide Distribution: 85,000
Worldwide Confirmed Malfunctions: 19

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[44] Low-voltage capacitors	3	1	
[47] Integrated circuit	1	3	
[59] Titanium case material	-	1	
Mechanical	**-**	**-**	**0**
Software	**5**	**-**	**5**
[48] Memory errors	5	-	
Other	**2**	**3**	**5**
Non-patterned	2	3	
WW Confirmed Malfunctions	**11**	**8**	**19**

More details about malfunctions

References cited in table above

ALTRUA 60 DR

Model S602

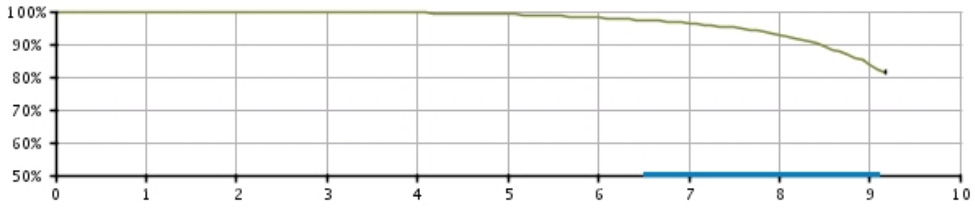
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

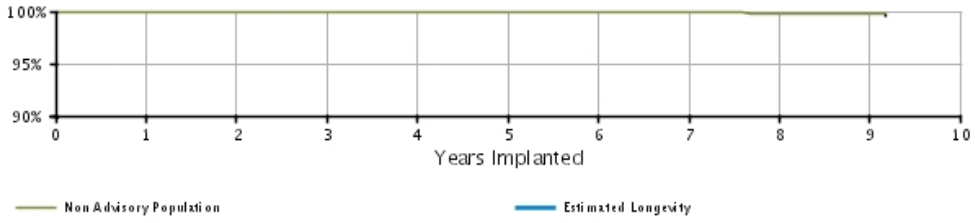
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 13,000

U.S. Normal Battery Depletions: 876
U.S. Unconfirmed Reports of Premature Battery Depletion : 6
U.S. Malfunctions:20
Without Compromised Therapy:19
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	Depletions and Malfunctions(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.03 (-0.2/+0.2)	98.04 (-0.3/+0.2)	96.43 (-0.4/+0.3)	92.96 (-0.6/+0.5)	83.99 (-1.3/+1.2)	81.44 @ 110 mo. (-1.8/+1.6)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.72 (-0.2/+0.1)	99.72 @ 110 mo. (-0.2/+0.1)
	Effective Sample Size	19585	17354	15318	13406	11609	9545	7502	5213	1038	409

ALTRUA 60 DR

Model S602

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 60 DR Model S602

Worldwide Distribution: 56,000
Worldwide Confirmed Malfunctions: 30

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[12] Capacitor	1	-	
Mechanical	**1**	**1**	**2**
[13] Capacitor array	1	-	
[38] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**25**	**2**	**27**
Non-patterned	2	1	
[23] Battery depletion	1	1	
[46] Battery status	22	-	
WW Confirmed Malfunctions	**27**	**3**	**30**

More details about malfunctions

References cited in table above

ALTRUA 60 DR (Downsize)

Model S603

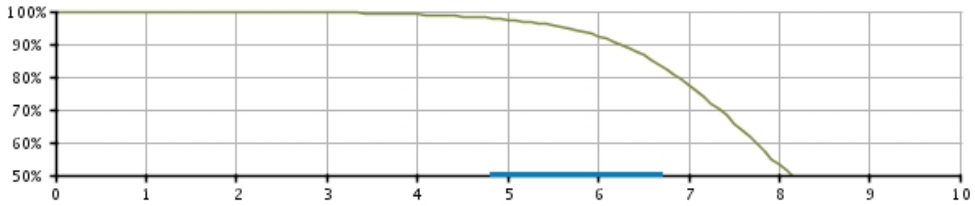
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

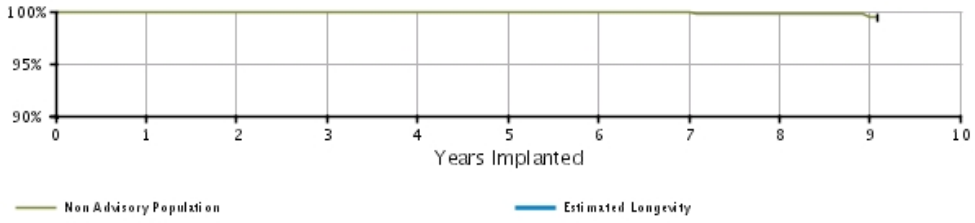
U.S. Registered Implants: 90,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 43,000

U.S. Normal Battery Depletions: 12,284
U.S. Unconfirmed Reports of Premature Battery Depletion : 46
U.S. Malfunctions:74
Without Compromised Therapy:65
With Compromised Therapy:9

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 90000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.09 (-0.1/+0.1)	97.46 (-0.1/+0.1)	92.47 (-0.3/+0.2)	77.42 (-0.5/+0.5)	53.01 (-0.8/+0.8)	30.91 (-1.3/+1.3)	29.09 @ 109 mo. (-1.4/+1.5)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.85 (-0.0/+0.0)	99.76 (-0.1/+0.1)	99.51 (-0.6/+0.3)	99.51 @ 109 mo. (-0.6/+0.3)
	Effective Sample Size	79405	70671	62789	55460	47332	32878	17264	5638	530	297

ALTRUA 60 DR (Downsize)

Model S603

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 60 DR (Downsize) Model S603

Worldwide Distribution: 132,000
Worldwide Confirmed Malfunctions: 94

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**8**	**13**
[12] Capacitor	4	7	
[27] Integrated circuit	1	1	
Mechanical	**2**	**1**	**3**
[9] Solder bond	-	1	
[36] Connector block	1	-	
[38] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**75**	**3**	**78**
Non-patterned	3	2	
[18] Magnet response	2	-	
[23] Battery depletion	3	1	
[46] Battery status	67	-	
WW Confirmed Malfunctions	**82**	**12**	**94**

More details about malfunctions

References cited in table above

ALTRUA 60 DR EL

Model S606

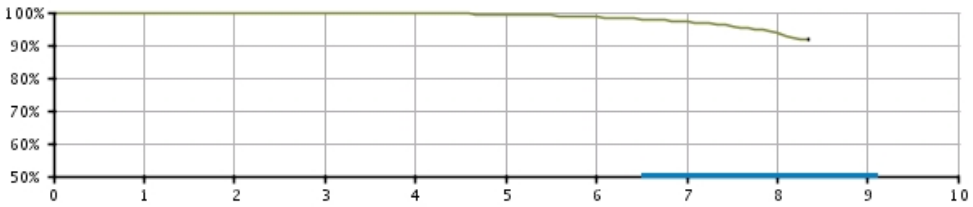
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

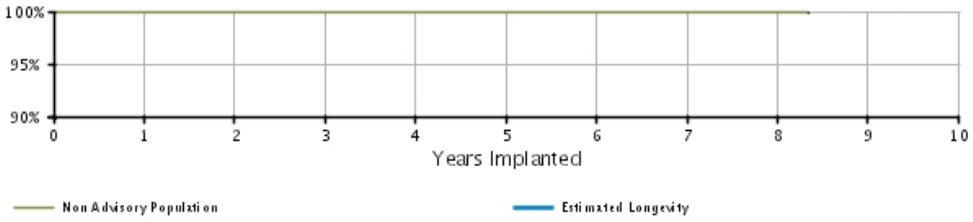
U.S. Registered Implants: 59,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 40,000

U.S. Normal Battery Depletions: 789
U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Malfunctions:15

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 59000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.70 (-0.1/+0.0)	99.34 (-0.1/+0.1)	98.56 (-0.1/+0.1)	97.12 (-0.3/+0.2)	93.73 (-0.7/+0.6)	91.95 @ 100 mo. (-1.1/+1.0)	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.90 (-0.2/+0.1)	99.90 @ 100 mo. (-0.2/+0.1)	–
	Effective Sample Size	52722	46895	41630	36816	31579	20261	9412	1685	265	–

ALTRUA 60 DR EL

Model S606

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 60 DR EL
Model S606

Worldwide Distribution: 90,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**-**	**4**
[12] Capacitor	3	-	
[14] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[38] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**9**	**2**	**11**
Non-patterned	1	-	
[23] Battery depletion	-	2	
[46] Battery status	8	-	
WW Confirmed Malfunctions	**13**	**3**	**16**

More details about malfunctions

References cited in table above

ALTRUA 60 SR

Model S601

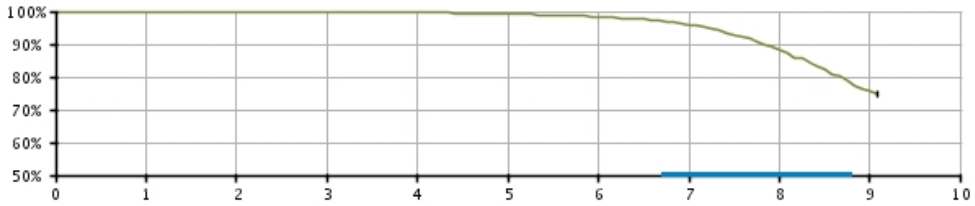
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

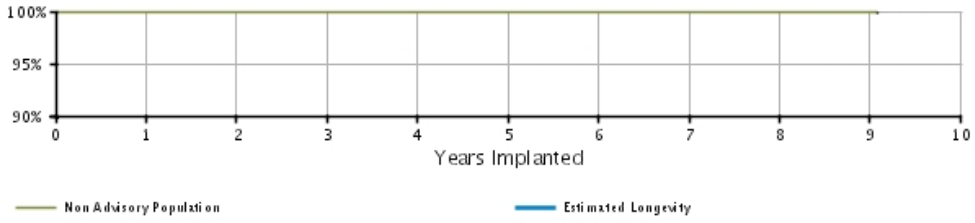
U.S. Registered Implants: 32,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 15,000

U.S. Normal Battery Depletions: 974
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:11
Without Compromised Therapy:9
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 32000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.80 (-0.1/+0.0)	99.62 (-0.1/+0.1)	99.16 (-0.1/+0.1)	98.35 (-0.2/+0.2)	96.00 (-0.4/+0.4)	88.10 (-0.9/+0.9)	75.83 (-2.1/+2.0)	74.88 @ 109 mo. (-2.4/+2.2)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.93 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.86 (-0.1/+0.1)	99.86 @ 109 mo. (-0.1/+0.1)
	Effective Sample Size	26727	23534	20911	18452	15749	10923	6430	2686	363	237

ALTRUA 60 SR

Model S601

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 60 SR
Model S601

Worldwide Distribution: 68,000
Worldwide Confirmed Malfunctions: 21

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[12] Capacitor	1	2	
[27] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**13**	**3**	**16**
Non-patterned	1	2	
[23] Battery depletion	-	1	
[46] Battery status	12	-	
WW Confirmed Malfunctions	**14**	**7**	**21**

More details about malfunctions

References cited in table above

ALTRUA 50 DR (Downsize)

Model S502

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 50 DR (Downsize) Model S502

Worldwide Distribution: 48,000
Worldwide Confirmed Malfunctions: 26

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**1**	**4**
[12] Capacitor	2	1	
[27] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[38] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**21**	**-**	**21**
Non-patterned	1	-	
[23] Battery depletion	2	-	
[46] Battery status	18	-	
WW Confirmed Malfunctions	**24**	**2**	**26**

More details about malfunctions

References cited in table above

ALTRUA 50 SR

Model S501

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 50 SR
Model S501

Worldwide Distribution: 25,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[12] Capacitor	1	4	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**3**	**4**
Non-patterned	-	1	
[23] Battery depletion	-	2	
[46] Battery status	1	-	
WW Confirmed Malfunctions	**2**	**7**	**9**

More details about malfunctions

References cited in table above

ALTRUA 50 DDD (Downsize)

Model S503

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 50 DDD (Downsize) Model S503

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**6**	**3**	**9**
Non-patterned	-	-	
[23] Battery depletion	-	3	
[46] Battery status	6	-	
WW Confirmed Malfunctions	**6**	**3**	**9**

More details about malfunctions

References cited in table above

ALTRUA 50 VDD (Downsize)

Model S504

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 50 VDD (Downsize) Model S504

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
[46] Battery status	2	-	
WW Confirmed Malfunctions	2	0	2

More details about malfunctions

References cited in table above

ALTRUA 50 SSI

Model S508

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 50 SSI Model S508

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**3**	**1**	**4**
Non-patterned	-	-	
[23] Battery depletion	-	1	
[46] Battery status	3	-	
WW Confirmed Malfunctions	**3**	**1**	**4**

More details about malfunctions

References cited in table above

ALTRUA 40 DR

Model S402

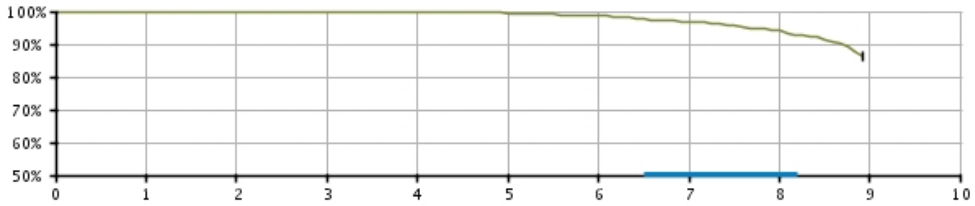
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

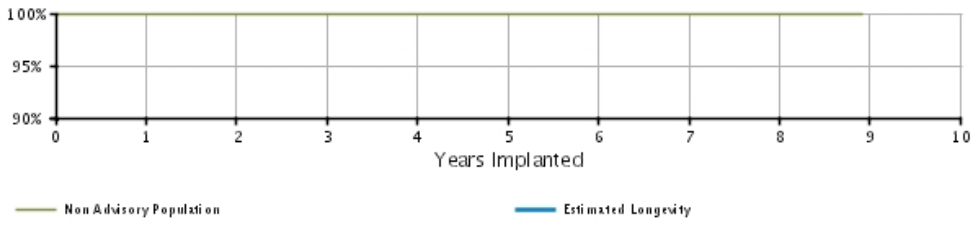
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 83
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.93 (-0.4/+0.1)	99.93 (-0.4/+0.1)	99.66 (-0.6/+0.2)	99.45 (-0.7/+0.3)	98.66 (-1.0/+0.6)	96.78 (-1.4/+1.0)	94.06 (-1.9/+1.5)	86.36 @ 107 mo. (-3.5/+2.8)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 107 mo. (-0.0/+0.0)	–
	Effective Sample Size	1517	1346	1194	1064	945	835	728	618	212	–

ALTRUA 40 DR

Model S402

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 40 DR
Model S402

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	-	
[23] Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

More details about malfunctions

References cited in table above

ALTRUA 40 DR (downsize)

Model S403

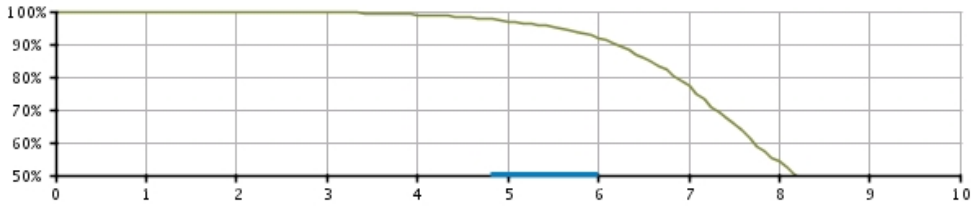
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

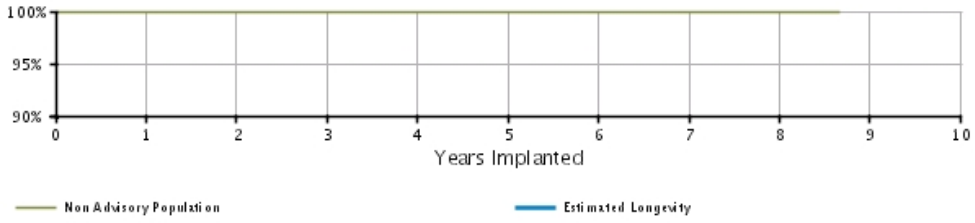
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 1,926
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:3
Without Compromised Therapy:3
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.69 (-0.1/+0.1)	98.95 (-0.2/+0.2)	96.95 (-0.4/+0.3)	91.92 (-0.7/+0.6)	77.01 (-1.2/+1.2)	54.12 (-1.9/+1.9)	40.91 @ 104 mo. (-2.6/+2.6)	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 104 mo. (-0.1/+0.0)	–
	Effective Sample Size	12514	11156	9913	8776	7650	5372	2687	832	223	–

ALTRUA 40 DR (downsize)

Model S403

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 40 DR (downsize) Model S403

Worldwide Distribution: 22,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**2**	**-**	**2**
[37] Seal plug	1	-	
[38] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**2**	**-**	**2**
Non-patterned	-	-	
[46] Battery status	2	-	
WW Confirmed Malfunctions	**4**	**0**	**4**

More details about malfunctions

References cited in table above

ALTRUA 40 DR EL

Model S404

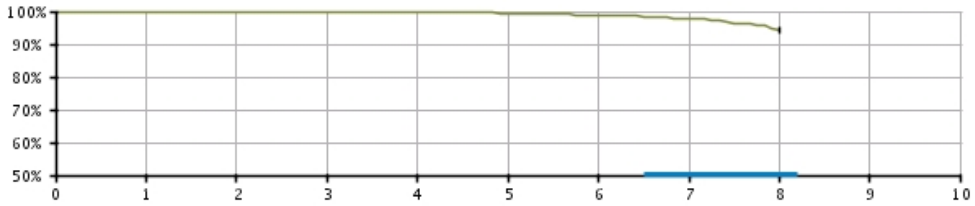
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

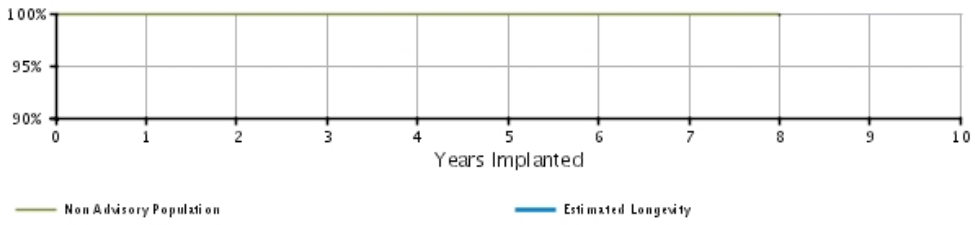
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 66
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:1
Without Compromised Therapy:1
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.68 (-0.3/+0.1)	99.41 (-0.3/+0.2)	98.63 (-0.5/+0.4)	97.91 (-0.7/+0.5)	94.44 (-2.1/+1.6)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	–	–
	Effective Sample Size	4474	3985	3561	3158	2783	1950	1070	228	–	–

ALTRUA 40 DR EL

Model S404

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 40 DR EL
Model S404

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[12] Capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	-	-	
[46] Battery status	1	-	
WW Confirmed Malfunctions	**2**	**0**	**2**

More details about malfunctions

References cited in table above

ALTRUA 40 SR

Model S401

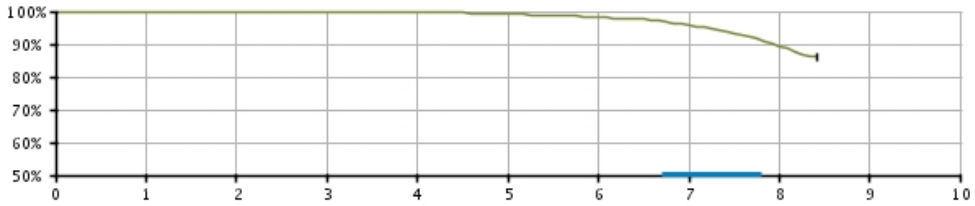
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

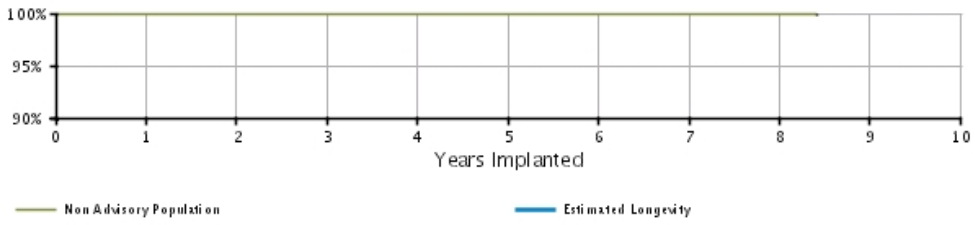
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 131
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:2
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.66 (-0.3/+0.2)	99.31 (-0.4/+0.2)	98.23 (-0.6/+0.5)	95.80 (-1.1/+0.9)	89.18 (-2.4/+2.0)	86.10 @ 101 mo. (-3.0/+2.6)	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 @ 101 mo. (-0.2/+0.0)	–
	Effective Sample Size	3952	3459	3030	2691	2371	1715	978	421	231	–

ALTRUA 40 SR

Model S401

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 40 SR Model S401

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**1**	**3**
[12] Capacitor	2	-	
[27] Integrated circuit	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 DR

Models S202/S205

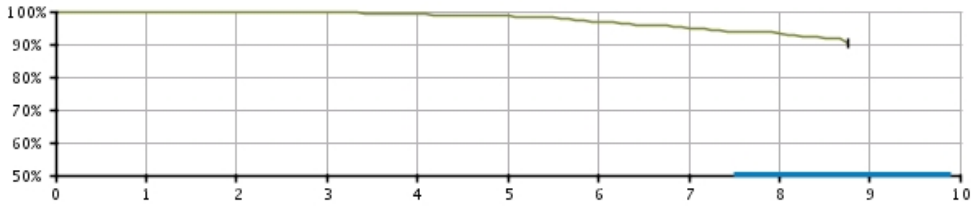
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

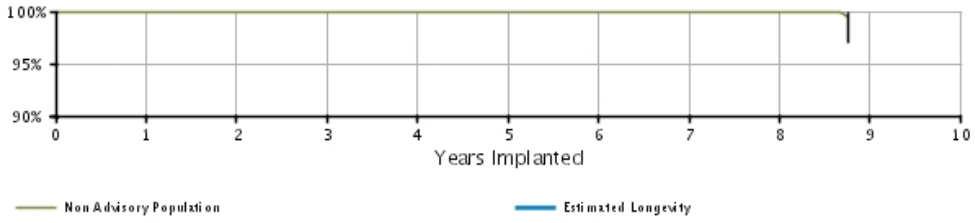
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 63
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:1
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.93 (-0.4/+0.1)	99.69 (-0.5/+0.2)	99.22 (-0.7/+0.4)	98.59 (-0.9/+0.6)	96.81 (-1.4/+1.0)	94.82 (-1.8/+1.4)	93.12 (-2.1/+1.7)	90.39 @ 105 mo. (-3.0/+2.3)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.42 @ 105 mo. (-2.5/+0.5)	–
	Effective Sample Size	1543	1352	1163	1000	856	709	571	454	203	–

ALTRUA 20 DR

Models S202/S205

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 20 DR Models S202/S205

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	-	-	
[23] Battery depletion	-	1	
[41] Magnet rate	1	-	
WW Confirmed Malfunctions	1	1	2

More details about malfunctions

References cited in table above

ALTRUA 20 DR (downsize)

Model S203

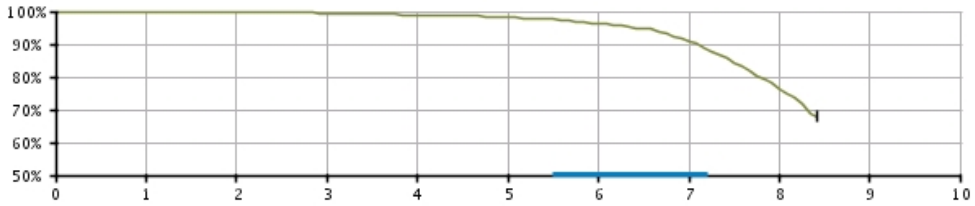
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

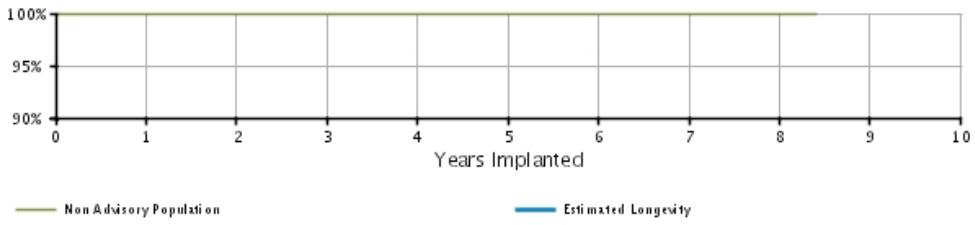
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 360
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.42 (-0.3/+0.2)	98.87 (-0.4/+0.3)	98.17 (-0.5/+0.4)	96.31 (-0.8/+0.6)	90.88 (-1.4/+1.2)	76.22 (-2.8/+2.6)	67.94 @ 101 mo. (-3.7/+3.5)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 101 mo. (-0.0/+0.0)	–
	Effective Sample Size	4401	3887	3454	3061	2686	1995	1157	455	226	–

ALTRUA 20 DR (downsize)

Model S203

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 20 DR (downsize) Model S203

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**-**	**2**
[12] Capacitor	2	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	-	
[23] Battery depletion	-	1	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 DR EL

Model S208

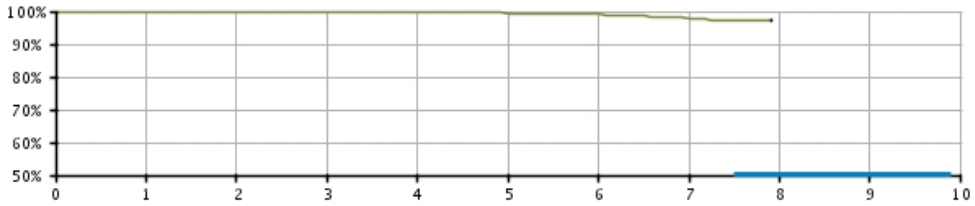
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

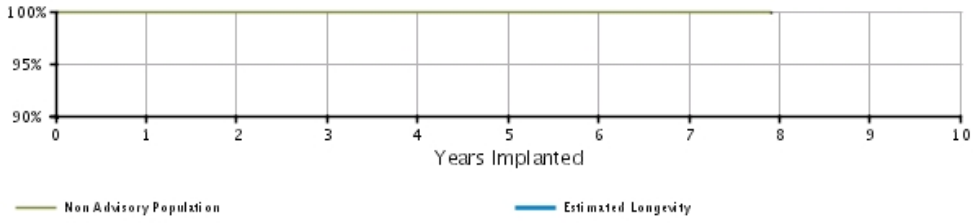
U.S. Registered Implants: 3,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 30
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:0
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.2/+0.0)	99.86 (-0.2/+0.1)	99.77 (-0.3/+0.1)	99.62 (-0.3/+0.2)	99.46 (-0.4/+0.2)	99.03 (-0.6/+0.4)	97.86 (-1.1/+0.7)	97.23 @ 95 mo. (-1.4/+0.9)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 95 mo. (-0.2/+0.0)	–	–
	Effective Sample Size	2772	2467	2188	1955	1712	1195	616	203	–	–

ALTRUA 20 DR EL

Model S208

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 20 DR EL
Model S208

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**2**	**2**
[12] Capacitor	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	1	
WW Confirmed Malfunctions	**0**	**3**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 SR

Models S201/S204

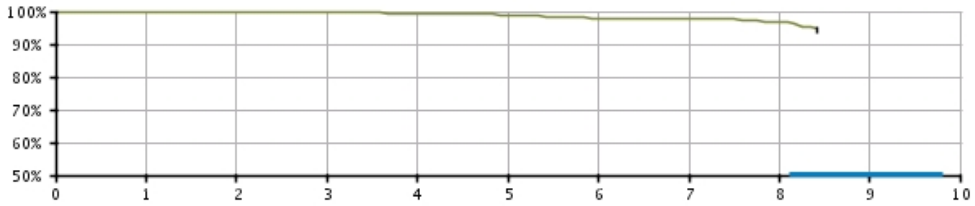
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

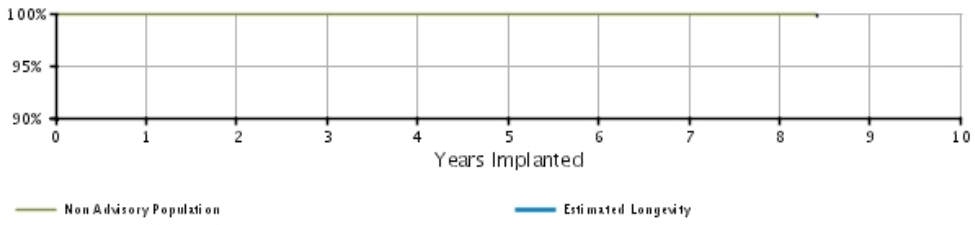
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 60
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:2
Without Compromised Therapy:2
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.67 (-0.3/+0.2)	99.34 (-0.4/+0.2)	98.76 (-0.5/+0.4)	97.83 (-0.7/+0.6)	97.55 (-0.8/+0.6)	96.73 (-1.3/+0.9)	94.62 @ 101 mo. (-2.4/+1.7)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.94 (-0.4/+0.0)	99.94 (-0.4/+0.0)	99.94 (-0.4/+0.0)	99.94 @ 101 mo. (-0.4/+0.0)	–
	Effective Sample Size	3613	3070	2613	2271	1926	1401	845	368	213	–

ALTRUA 20 SR

Models S201/S204

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 20 SR Models S201/S204

Worldwide Distribution: 24,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[12] Capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**2**	**1**	**3**
Non-patterned	-	1	
[46] Battery status	2	-	
WW Confirmed Malfunctions	**3**	**1**	**4**

More details about malfunctions

References cited in table above

ALTRUA 20 SSI

Model S206

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 20 SSI Model S206

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

ALTRUA 20 DDD

Model S207

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 20 DDD Model S207

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

INSIGNIA Ultra DR

Model 1291

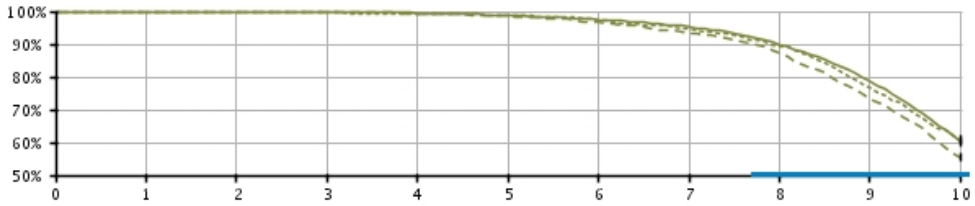
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

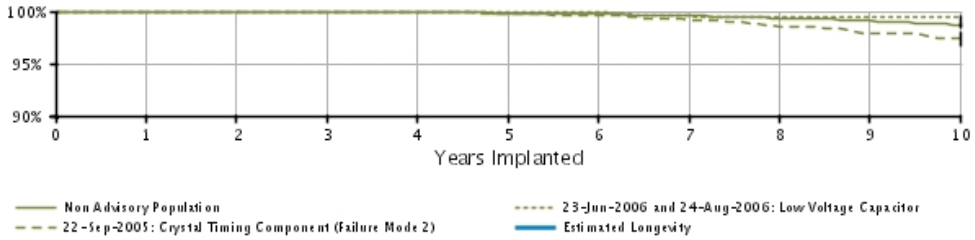
U.S. Registered Implants: 32,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 5,673
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:193
Without Compromised Therapy:179
With Compromised Therapy:14

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 24000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.1/+0.0)	99.50 (-0.1/+0.1)	98.71 (-0.2/+0.2)	97.43 (-0.3/+0.3)	95.30 (-0.4/+0.4)	89.76 (-0.6/+0.6)	78.57 (-0.9/+0.8)	60.47 (-1.2/+1.2)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.36 (-0.2/+0.1)	99.07 (-0.2/+0.2)	98.70 (-0.3/+0.2)
	Effective Sample Size	21001	18656	16557	14647	12903	11295	9791	8150	6240	2426
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.3/+0.1)	99.79 (-0.3/+0.1)	99.59 (-0.5/+0.2)	99.30 (-0.6/+0.3)	98.80 (-0.7/+0.5)	97.47 (-1.1/+0.8)	94.62 (-1.5/+1.2)	89.39 (-2.2/+1.8)	76.96 (-3.1/+2.8)	60.37 (-3.7/+3.6)
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.63 (-0.6/+0.2)	99.38 (-0.8/+0.3)	99.38 (-0.8/+0.3)	99.38 (-0.8/+0.3)
	Effective Sample Size	1877	1658	1459	1286	1131	984	843	692	519	349
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.58 (-0.7/+0.6)	93.41 (-0.9/+0.8)	87.17 (-1.3/+1.2)	73.47 (-1.8/+1.7)	55.47 (-2.1/+2.1)

	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.89 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.62 (-0.3/+0.2)	99.15 (-0.4/+0.3)	98.58 (-0.5/+0.4)	97.95 (-0.7/+0.5)	97.38 (-0.8/+0.6)
	Effective Sample Size	5702	5046	4467	3938	3451	2978	2553	2094	1549	992

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra DR

Model 1291

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Ultra DR Model 1291

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 240

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**5**	**12**
[5] Low-voltage capacitor (Advisory issued)	-	2	
[11] Capacitor	1	-	
[12] Capacitor	4	2	
[27] Integrated circuit	2	1	
Mechanical	**8**	**5**	**13**
[16] Seal plug	5	4	
[17] Header	2	1	
[29] Setscrew	1	-	
Software	**4**	**-**	**4**
[31] Underestimation of battery status	3	-	
[33] Pacing rate limit	1	-	
Other	**202**	**9**	**211**
Non-patterned	9	8	
[8] Longevity labeling	75	-	
[18] Magnet response	1	-	
[23] Battery depletion	3	1	
[46] Battery status	114	-	
WW Confirmed Malfunctions	**221**	**19**	**240**

More details about malfunctions

References cited in table above

INSIGNIA Ultra SR

Model 1190

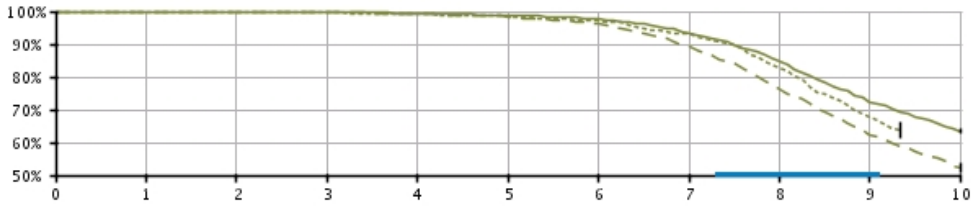
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

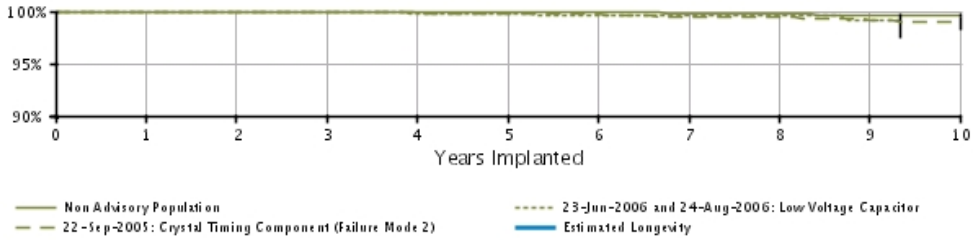
U.S. Registered Implants: 24,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 2,988
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:43
Without Compromised Therapy:39
With Compromised Therapy:4

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.70 (-0.1/+0.1)	99.40 (-0.2/+0.1)	98.72 (-0.3/+0.2)	97.53 (-0.4/+0.3)	93.44 (-0.6/+0.6)	84.58 (-0.9/+0.9)	72.50 (-1.2/+1.2)	63.50 (-1.4/+1.4)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.70 (-0.2/+0.1)	99.65 (-0.2/+0.1)	99.62 (-0.2/+0.1)
	Effective Sample Size	14136	12067	10279	8810	7667	6702	5704	4548	3365	1550
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.5/+0.1)	99.73 (-0.6/+0.2)	99.51 (-0.7/+0.3)	99.10 (-0.9/+0.5)	98.46 (-1.2/+0.7)	97.20 (-1.6/+1.0)	93.18 (-2.5/+1.9)	82.96 (-3.8/+3.2)	67.70 (-4.8/+4.5)	63.99 @ 112 mo. (-5.0/+4.7)
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.77 (-0.7/+0.2)	99.77 (-0.7/+0.2)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.19 (-1.7/+0.5)	99.19 @ 112 mo. (-1.7/+0.5)
	Effective Sample Size	1146	961	810	696	585	496	414	325	226	201
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.98 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.81 (-0.2/+0.1)	99.22 (-0.4/+0.3)	98.27 (-0.6/+0.4)	96.24 (-0.9/+0.7)	89.32 (-1.5/+1.3)	76.20 (-2.2/+2.1)	62.28 (-2.6/+2.5)	52.37 (-2.8/+2.8)

Component (Failure Mode 2)* Registered Implants: 5000	(Confidence Interval)									
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.78 (-0.3/+0.1)	99.47 (-0.4/+0.2)	99.40 (-0.5/+0.3)	99.16 (-0.7/+0.4)	99.01 (-0.8/+0.4)
	Effective Sample Size	4143	3554	2996	2524	2107	1764	1413	1024	724	520

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra SR

Model 1190

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Ultra SR Model 1190

Worldwide Distribution: 48,000
Worldwide Confirmed Malfunctions: 78

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**5**	**7**
[5] Low-voltage capacitor (Advisory issued)	1	3	
[12] Capacitor	1	-	
[27] Integrated circuit	-	2	
Mechanical	**3**	**1**	**4**
[16] Seal plug	3	-	
[17] Header	-	1	
Software	**1**	**-**	**1**
[20] Memory error	1	-	
Other	**66**	**-**	**66**
Non-patterned	1	-	
[8] Longevity labeling	23	-	
[23] Battery depletion	2	-	
[46] Battery status	40	-	
WW Confirmed Malfunctions	**72**	**6**	**78**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR

Models 1294/1295

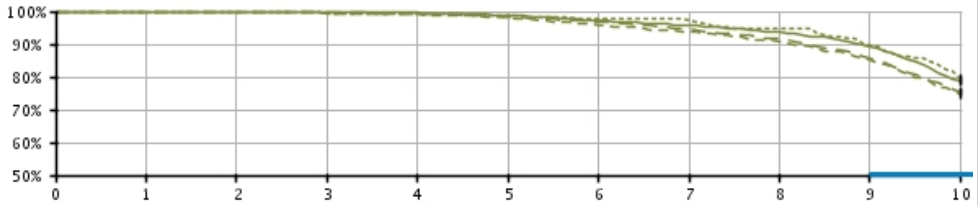
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

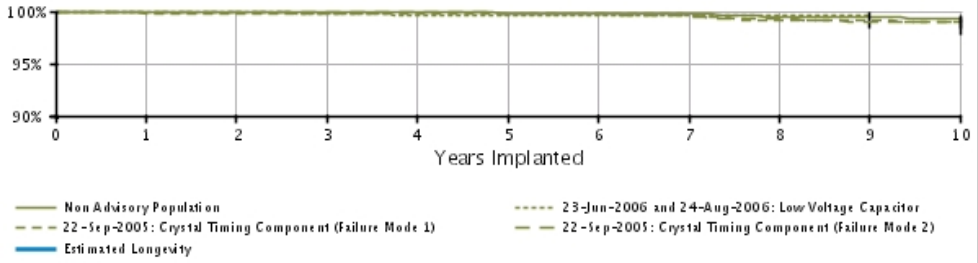
U.S. Registered Implants: 17,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 2,265
U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Malfunctions:69
Without Compromised Therapy:61
With Compromised Therapy:8

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.87 (-0.1/+0.1)	99.75 (-0.2/+0.1)	99.51 (-0.2/+0.2)	98.72 (-0.4/+0.3)	97.04 (-0.6/+0.5)	95.65 (-0.7/+0.6)	93.53 (-0.9/+0.8)	89.43 (-1.2/+1.1)	78.78 (-1.8/+1.7)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.44 (-0.3/+0.2)	99.33 (-0.4/+0.2)
	Effective Sample Size	6261	5547	4913	4353	3804	3303	2889	2515	2086	1141
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.45 (-1.1/+0.4)	99.23 (-1.3/+0.5)	98.75 (-1.5/+0.7)	97.65 (-2.0/+1.1)	97.32 (-2.1/+1.2)	94.51 (-3.1/+2.0)	89.82 (-4.2/+3.1)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.82 (-1.1/+0.2)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	–
	Effective Sample Size	693	607	528	451	393	336	292	245	201	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.69 (-0.4/+0.2)	99.46 (-0.5/+0.3)	99.19 (-0.7/+0.4)	98.09 (-1.0/+0.7)	95.93 (-1.4/+1.1)	93.68 (-1.8/+1.4)	90.90 (-2.2/+1.8)	85.16 (-2.9/+2.5)	74.93 (-3.8/+3.4)

	Malfunctions Only(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.67 (-0.6/+0.2)	99.18 (-1.0/+0.5)	99.18 (-1.0/+0.5)	98.94 (-1.2/+0.6)
	Effective Sample Size	1676	1453	1212	1062	922	783	659	552	449	331
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.71 (-0.2/+0.1)	99.31 (-0.3/+0.2)	98.37 (-0.4/+0.3)	96.89 (-0.6/+0.5)	94.56 (-0.8/+0.7)	91.52 (-1.0/+0.9)	85.53 (-1.4/+1.3)	75.35 (-1.8/+1.7)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.47 (-0.3/+0.2)	99.31 (-0.4/+0.2)	98.97 (-0.5/+0.3)	98.91 (-0.5/+0.3)
	Effective Sample Size	6207	5479	4821	4227	3690	3184	2673	2255	1842	1392

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra DR

Models 1294/1295

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Entra DR Models 1294/1295

Worldwide Distribution: 37,000
Worldwide Confirmed Malfunctions: 85

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[10] Integrated circuit	-	1	
[12] Capacitor	-	1	
[27] Integrated circuit	-	1	
Mechanical	**3**	**7**	**10**
[6] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[16] Seal plug	3	-	
[17] Header	-	2	
Software	**1**	**-**	**1**
[31] Underestimation of battery status	1	-	
Other	**66**	**5**	**71**
Non-patterned	4	5	
[8] Longevity labeling	49	-	
[46] Battery status	13	-	
WW Confirmed Malfunctions	**70**	**15**	**85**

More details about malfunctions

References cited in table above

INSIGNIA Entra SR

Models 1195/1198

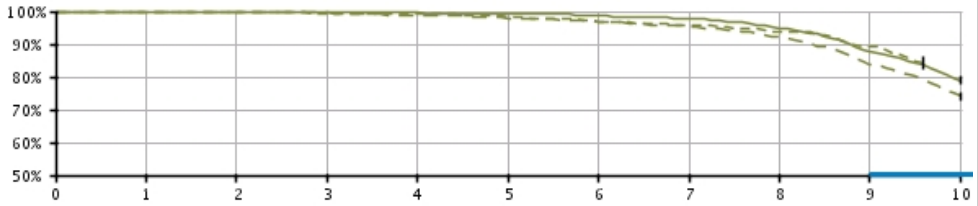
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

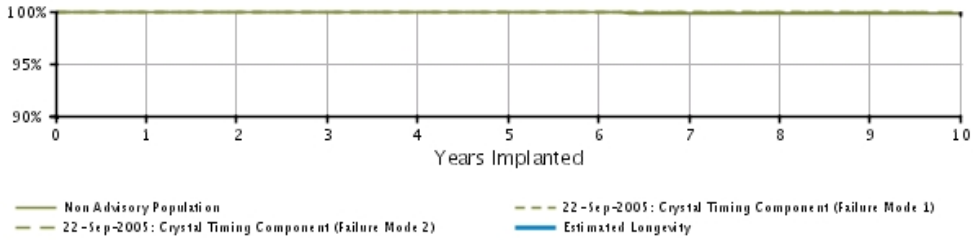
U.S. Registered Implants: 14,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 1,072
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:9
Without Compromised Therapy:7
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.1)	99.85 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.36 (-0.4/+0.2)	98.74 (-0.5/+0.4)	97.88 (-0.7/+0.5)	94.84 (-1.1/+0.9)	87.86 (-1.7/+1.5)	78.94 (-2.4/+2.2)
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)
	Effective Sample Size	4707	3870	3247	2730	2302	1967	1713	1461	1145	616
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.84 (-0.5/+0.1)	99.50 (-0.7/+0.3)	99.20 (-0.9/+0.4)	98.19 (-1.3/+0.8)	96.95 (-1.8/+1.1)	95.71 (-2.1/+1.5)	93.92 (-2.7/+1.9)	89.40 (-3.7/+2.8)	84.27 @ 115 mo. (-4.5/+3.6)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 115 mo. (-0.0/+0.0)
	Effective Sample Size	1215	997	805	660	548	445	354	296	242	202
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.96 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.58 (-0.3/+0.2)	98.79 (-0.4/+0.3)	97.94 (-0.6/+0.5)	96.94 (-0.8/+0.6)	95.24 (-1.0/+0.8)	92.15 (-1.3/+1.2)	84.00 (-2.0/+1.8)	74.25 (-2.5/+2.3)

Component (Failure Mode 2)* Registered Implants: 6000	(Confidence Interval)										
	Malfunctions Only (%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)
	Effective Sample Size	4575	3824	3171	2631	2174	1817	1527	1272	1007	772

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra SR

Models 1195/1198

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Entra SR Models 1195/1198

Worldwide Distribution: 52,000
Worldwide Confirmed Malfunctions: 29

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**4**	**7**
[5] Low-voltage capacitor (Advisory issued)	-	2	
[12] Capacitor	2	2	
[27] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[6] Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
[7] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[13] Capacitor array	-	2	
[16] Seal plug	-	2	
[30] Seal plug	-	1	
Software	**-**	**-**	**0**
Other	**12**	**3**	**15**
Non-patterned	1	2	
[8] Longevity labeling	6	-	
[23] Battery depletion	-	1	
[46] Battery status	5	-	
WW Confirmed Malfunctions	**16**	**13**	**29**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR

Model 1297

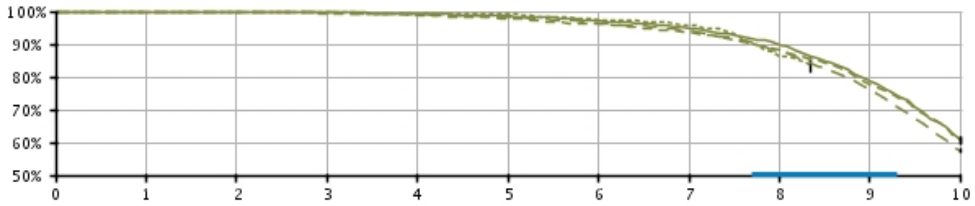
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

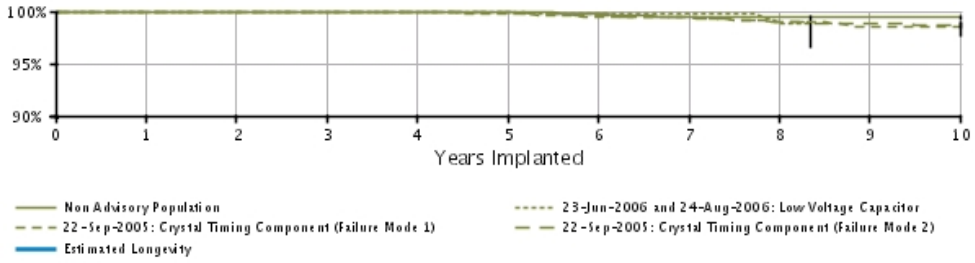
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 5,912
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:131
Without Compromised Therapy:122
With Compromised Therapy:9

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.75 (-0.2/+0.1)	99.26 (-0.3/+0.2)	98.51 (-0.4/+0.3)	97.16 (-0.6/+0.5)	94.98 (-0.7/+0.7)	89.81 (-1.1/+1.0)	78.55 (-1.5/+1.5)	60.90 (-2.1/+2.0)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.49 (-0.3/+0.2)	99.38 (-0.3/+0.2)	99.38 (-0.3/+0.2)	99.38 (-0.3/+0.2)
	Effective Sample Size	6560	5831	5160	4545	3996	3495	3029	2530	1940	891
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.18 (-1.3/+0.5)	99.18 (-1.3/+0.5)	97.24 (-2.2/+1.2)	95.94 (-2.6/+1.6)	86.19 (-4.5/+3.5)	83.71 @ 100 mo. (-4.8/+3.9)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.73 (-1.6/+0.2)	99.73 (-1.6/+0.2)	98.85 (-2.4/+0.8)	98.85 @ 100 mo. (-2.4/+0.8)	–
	Effective Sample Size	664	580	510	441	385	333	284	220	201	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.89 (-0.5/+0.3)	97.87 (-0.7/+0.5)	96.19 (-0.9/+0.7)	93.52 (-1.2/+1.0)	88.08 (-1.7/+1.5)	77.78 (-2.2/+2.1)	60.51 (-2.8/+2.7)

	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.81 (-0.3/+0.1)	99.48 (-0.4/+0.2)	99.42 (-0.5/+0.3)	99.04 (-0.6/+0.4)	98.57 (-0.8/+0.5)	98.45 (-0.8/+0.5)
	Effective Sample Size	3514	3072	2597	2280	1970	1703	1455	1208	926	609
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.89 (-0.1/+0.0)	99.55 (-0.1/+0.1)	99.10 (-0.2/+0.2)	98.16 (-0.3/+0.3)	96.48 (-0.4/+0.4)	94.04 (-0.6/+0.5)	87.77 (-0.8/+0.8)	76.04 (-1.2/+1.1)	57.50 (-1.4/+1.4)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.1)	99.58 (-0.2/+0.1)	99.38 (-0.2/+0.2)	99.05 (-0.3/+0.2)	98.80 (-0.3/+0.3)	98.70 (-0.3/+0.3)
	Effective Sample Size	12755	11251	9911	8722	7618	6593	5625	4604	3461	2240

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Plus and Intermedics NEXUS Plus device performance.

INSIGNIA Plus DR

Model 1297

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Plus DR Model 1297

Worldwide Distribution: 47,000
Worldwide Confirmed Malfunctions: 170

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**3**	**6**
[5] Low-voltage capacitor (Advisory issued)	1	1	
[12] Capacitor	2	1	
[27] Integrated circuit	-	1	
Mechanical	**17**	**9**	**26**
[6] Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
[7] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[9] Solder bond	1	-	
[13] Capacitor array	1	-	
[16] Seal plug	6	-	
[17] Header	8	6	
Software	**7**	**-**	**7**
[31] Underestimation of battery status	4	-	
[32] Interrupted telemetry	2	-	
[33] Pacing rate limit	1	-	
Other	**126**	**5**	**131**
Non-patterned	7	5	
[8] Longevity labeling	88	-	
[23] Battery depletion	2	-	
[46] Battery status	29	-	
WW Confirmed Malfunctions	**153**	**17**	**170**

More details about malfunctions

References cited in table above

INSIGNIA AVT

Models 0482/0882/0982/1192/1292

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA AVT
Models 0482/0882/0982/1192/1292

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 110

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**5**	**5**
[5] Low-voltage capacitor (Advisory issued)	-	3	
[12] Capacitor	-	1	
[27] Integrated circuit	-	1	
Mechanical	**2**	**-**	**2**
[16] Seal plug	1	-	
[17] Header	1	-	
Software	**-**	**-**	**0**
Other	**101**	**2**	**103**
Non-patterned	3	1	
[8] Longevity labeling	42	-	
[23] Battery depletion	-	1	
[46] Battery status	56	-	
WW Confirmed Malfunctions	**103**	**7**	**110**

More details about malfunctions

References cited in table above

References

Descriptions listed below provide an overview of the clinical observations and/or analysis findings associated with each pulse generator confirmed malfunction pattern listed in this report.

All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, changes have been or will be implemented in response to identified malfunction patterns. "Improvements implemented" may include product design changes in existing or subsequent generations, manufacturing process modifications, software updates, educational communications, labeling changes, etc. Improvement implementation may vary by geography due to various factors, including regulatory review timing, and may not completely mitigate or eliminate the potential for additional malfunctions.

1. **Memory corruption**— *Jun 2017 Voluntary Physician Advisory.* Atypical energy delivery, error messages upon interrogation, loss of tachy therapy. Memory corruption. Improvement implemented.
2. **Low Voltage Capacitor 2014**— *Aug 2013 and Sep 2014 Voluntary Physician Advisory.* Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
3. **Subpectoral implant 2009**— *December 01, 2009 Voluntary Physician Advisory.* Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subpectorally. Weakened bond between header and titanium case. Improvement implemented.
4. **Respiratory Sensor Oversensing**— *March 23, 2009 Voluntary Physician Advisory.* Oversensing, noise, inappropriate shock, pacing inhibition. When Respiratory Sensor is ON, RV lead or system complications may cause oversensing or noise. Improvement implemented.
5. **Low-voltage capacitor**— *June 23, 2006 and August 24, 2006 Voluntary Physician Advisory.* Premature battery depletion, no output, no interrogation. Failed low-voltage capacitor. Improvement implemented.
6. **Crystal timing component Failure Mode 1**— *September 22, 2005 Voluntary Physician Advisory.* Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode or appearance of a reset warning message upon interrogation. Foreign material within a crystal timing component. Improvement implemented.
7. **Crystal timing component Failure Mode 2**— *September 22, 2005 Voluntary Physician Advisory.* At implant procedure or during pre-implant testing: Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode, or appearance of a reset warning message upon interrogation. Microscopic particle within a crystal timing component. Three failures have been reported following confirmation of successful implantation. No currently distributed devices are subject to this peri-implant failure mode. Improvement implemented.
8. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
9. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
10. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
11. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
12. **Capacitor**— No telemetry, no pacing, premature battery depletion. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor.
13. **Capacitor array**— Loss of device output, loss of capture, inability to accurately measure charge times causing elective replacement indicator declaration. Damage to capacitor array. Improvement implemented.
14. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
15. **Battery depletion**— Premature battery depletion and loss of capture.
16. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
17. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
18. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
19. **Battery depletion**— Premature battery depletion.
20. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
21. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
22. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
23. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.

24. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
25. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
26. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
27. **Integrated circuit**— Premature battery depletion, loss of pacing output, inability to interrogate, loss of sensing, high-rate pacing, loss of shock therapy. Damage to integrated circuit. Improvement implemented.
28. **Alert messages**— During programmer interactions, alert messages appear which are able to be cleared. In one case, an alert message occurred with two memory errors after multiple device resets.
29. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
30. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
31. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
32. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
33. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
34. **Solder joint**— Inappropriate shocks, beeping, fallback mode, errors or inability to interrogate or program. Cracked solder joint due to repetitive mechanical stress-induced component damage, only when implanted subpectorally with serial number facing the ribs.
35. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
36. **Connector block**— Connector block can be moved out of alignment or displaced from header. Prolonged implant procedure, high impedance, no pacing, no sensing. Improvement implemented.
37. **Seal plug**— Non-cardiac signals on electrograms may result in loss of pacing or inappropriate shocks. Seal plug allows air in lead port to escape.
38. **Difficulty securing lead**— Noise, high impedance, inappropriate shocks or loss of therapy due to crossthreaded setscrews, intermittent or lack of contact between lead and header. Improvement implemented.
39. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
40. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
41. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
42. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
43. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
44. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
45. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
46. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
47. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
48. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
49. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
50. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
51. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
52. **High cathode condition**— *June 1, 2011 Voluntary Physician Advisory.* Premature battery depletion. Misaligned battery component. Improvement implemented.
53. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
54. **Telemetry**— Inability to interrogate, premature battery depletion.
55. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory.* Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
56. **Unintended Battery Depletion Alert**— Beeping tones, Battery Depletion alert during followup despite normal battery depletion. Alert may be cleared without impact to battery status or therapy availability. Improvement implemented.
57. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
58. **Respiratory sensor**— Temporary increase or decrease in pacing rate as a result of respiratory sensor response to non-respiratory signals. No loss of pacing output.
59. **Titanium case material**— Noise, oversensing, abnormal pacing impedance, loss of capture, premature battery depletion. Titanium case material creating a higher than normal current drain condition. Improvement implemented.

60. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.

61. **High voltage circuit component**— Charge time alert message and/or Elective Replacement indicator (ERI) displayed, beeping tones. High voltage circuit component. Improvement implemented.

62. **Integrated circuit**— Abnormal lead impedance, no telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor Improvement implemented.

63. **High voltage capacitor**— Charge time alert message, end of life (EOL) indicator displayed, beeping tones. Loss of tachy therapy without loss of brady therapy. Internal high-voltage capacitor issue. Improvement implemented.

64. **Capacitor**— Premature battery depletion. Diminished low voltage capacitor performance.

65. **Telemetry**— Alert message during followup, inability to interrogate, premature battery depletion, loss of pacing therapy. Telemetry component.

66. **Header**— Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subcutaneously. Weakened bond between header and titanium case. Improvement Implemented.

Before/During Implant Procedure - Worldwide Malfunctions: Pulse Generators

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling (e.g. radiation) is not reported as device malfunction here.
The Electrical category is comprised of confirmed malfunctions involving electrical components such as batteries and capacitors, and also includes fault codes encountered at implant. The majority of before/during implant pulse generator confirmed malfunctions in the Mechanical category are issues occurring within the connector block (e.g. stuck setscrews, seal plug/ring issues). The Software category consists primarily of confirmed malfunctions that result in telemetry issues. Confirmed malfunctions in the Labeling and Packaging categories include product labeling/identification issues and damage to sterile packaging, respectively. The Other category is comprised of non-patterned confirmed malfunctions.

CRT-D/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/ G248/G324/G325/G347/G348/G424/G425/G426/G428/G437/ G447/G448/G524/G525/G526/G528/G537/G547/G548	2,000	0	0	0	0	0	0
AUTOGEN CRT-D G160/G161/G164/G166/G172/G173/G175/ G177/G179	21,000	3	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	64,000	3	2	1	7	0	0
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/ N143/N160/N161/N162/N163/N164/N165/ P052/P053/P142/P143/P162/P163/P165	81,000	10	0	0	10	0	0
COGNIS N118/N119/N120/P106/P107/P108	109,000	24	50	4	26	0	0
CONTAK RENEWAL 4 H190/H195	18,000	1	13	1	2	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE U128/U225	29,000	4	0	1	1	0	0
INTUA V272/V273/V282/V283/W272/W273	3,000	0	0	0	0	0	0
INVIVE V172/V173/V182/V183/W172/W173	18,000	0	0	1	2	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	8	0	2	0	0
CONTAK RENEWAL TR H120/H125	19,000	0	11	0	5	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
PERCIVA ICD DR D401/D413/D501/D513	100	0	0	0	0	0	0
AUTOGEN ICD EL VR D160/D161/D174/D175	12,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	11,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	32,000	1	0	1	1	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	31,000	0	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	15,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	14,000	2	0	0	2	0	0

ICD/Model, continued…	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	68,000	3	1	0	9	0	0
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	72,000	5	1	0	5	0	0
TELIGEN VR E102/E103/F102/F103	66,000	8	32	2	18	0	0
TELIGEN DR E110/E111/F110/F111	91,000	6	42	1	24	0	0
CONFIENT DR E030/F030	8,000	1	3	0	0	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	28,000	0	0	2	20	0	0
SQ-RX S-ICD 1010	11,000	11	0	21	23	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	82,000	2	0	1	1	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	169,000	2	0	1	6	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	59,000	0	0	1	4	0	0
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	72,000	1	1	0	3	0	0
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	217,000	4	0	1	15	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	85,000	0	0	1	4	0	0
INGENIO VDD J178/J179/K188	2,000	0	0	0	21	0	0
ALTRUA 60 SR S601	68,000	1	6	0	2	0	0
ALTRUA 60 DR EL S606	90,000	0	8	0	2	0	0
ALTRUA 60 DR (Downsize) S603	132,000	1	22	0	4	0	0
ALTRUA 60 DR S602	56,000	1	11	0	2	0	0
ALTRUA 50 SR S501	25,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	48,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	12,000	1	1	0	0	0	0
ALTRUA 50 VDD (Downsize) S504	6,000	0	0	0	0	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ALTRUA 50 SSI S508	6,000	0	0	0	1	0	0
ALTRUA 40 SR S401	9,000	0	2	0	0	0	0
ALTRUA 40 DR (Downsize) S403	22,000	0	4	0	2	0	0
ALTRUA 40 DR S402	3,000	1	3	0	0	0	0
ALTRUA 40 DR EL S404	11,000	0	0	0	0	0	0
ALTRUA 20 SR S201/S204	24,000	0	2	0	0	0	0
ALTRUA 20 DR (Downsize) S203	16,000	0	1	0	0	0	0
ALTRUA 20 DR S202/S205	3,000	1	0	0	1	0	0
ALTRUA 20 DR EL S208	11,000	0	0	0	0	0	0
ALTRUA 20 DDD S207	1,000	0	0	0	0	0	0
ALTRUA 20 SSI S206	8,000	0	0	0	1	0	0
INSIGNIA Ultra SR 1190*	48,000	3	3	1	4	0	0
INSIGNIA Ultra DR 1291*	51,000	1	8	1	4	0	0
INSIGNIA Entra SR 1195/1198*	52,000	1	0	3	5	0	0
INSIGNIA Entra DR 1294/1295*	37,000	0	6	3	9	0	0
INSIGNIA Plus DR 1297*	47,000	0	7	8	6	0	1
INSIGNIA AVT 0482/0882/0982/1192/1292*	51,000	1	1	0	3	0	0

*Counts consist of Boston Scientific and Intermedics co-branded pacemaker data.

U.S. Reason for Out of Service

As requested by the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines, Boston Scientific provides reasons for device explant or out of service, if known. The reasons consist of normal battery depletion, unconfirmed premature battery depletion, device upgrade, device malfunction (which includes devices under advisory that have experienced a malfunction), complication related to another system component or clinical condition, (such as infection), or "other," a category consisting of patient death, prophylactic device explant, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.

The counts for normal battery depletion, unconfirmed premature battery depletion, and device malfunction are reflected in the U.S. survival probability data. Reason for device explant or out of service may either be confirmed through laboratory analysis (as in the case of device malfunction) or it may be reported to Boston Scientific with no associated device return or laboratory analysis. Although a device may be indicated by the health care provider to have been taken out of service for more than one reason, the table below indicates only one reason per device in category counts.

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/ G148/G150/G151/G154/G156/G158	42000	4	4	64	15	484	2319
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/N143/N160/ N161/N162/N163/N164/N165/P052/P053/P142/P143/ P162/P163/P165	52000	312	53	142	346	974	11083
COGNIS N118/N119/N120/P106/P107/P108	75000	3298	131	147	1751	1785	32349

CRT-P/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
VISIONIST/VALITUDE U125/U128/U225/U226/U228	14000	1	1	151	7	98	731
INTUA V272/V273/V282/V283/W272/W273	3000	8	0	39	2	23	343
INVIVE V172/V173/V182/V183/W172/W173	8000	58	0	72	2	62	1777
CONTAK RENEWAL TR H120/H125	19000	3230	16	177	54	261	10179

S-ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
EMBLEM S-ICD A209, A219	14000	1	1	40	6	282	527
SQ-RX S-ICD 1010	8000	138	2	58	46	273	875

ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	22000	4	1	235	3	173	694
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	20000	1	2	229	3	148	577
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	6000	2	1	88	7	78	461
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	6000	3	0	98	4	72	439
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	57	25	726	159	529	5802
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	47000	52	22	900	214	649	7323

ICD/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
TELIGEN VR E102/E103/F102/F103	38000	104	127	930	1450	677	13001
TELIGEN DR E110/E111/F110/F111	66000	442	174	1377	2159	1195	23684
CONFIENT DR E030/F030	7000	970	2	201	14	159	3231

Pacemaker/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ACCOLADE/PROPONENT/ESSENTIO DR EL L121/L131/L221/L231/L321/L331	34000	6	4	303	10	147	804
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	89000	17	4	703	26	392	3394

Pacemaker/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	18000	5	1	228	6	87	1268
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	4	0	178	4	56	974
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	121000	191	15	1431	42	740	18778
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	22	1	311	8	148	6641
ALTRUA 60 SR S601	32000	974	4	315	11	177	15316
ALTRUA 60 DR (Downsize) S603	90000	12284	46	806	74	573	32219
ALTRUA 60 DR S602	22000	876	6	262	20	198	7876
ALTRUA 60 DR EL S606	59000	789	13	667	15	434	17257
ALTRUA 40 SR S401	5000	131	0	34	2	24	2466
ALTRUA 40 DR (downsize) S403	14000	1926	4	97	3	80	5315
ALTRUA 40 DR S402	2000	83	1	22	0	8	775
ALTRUA 40 DR EL S404	5000	66	2	48	1	43	1899
ALTRUA 20 SR S201/S204	5000	60	1	25	2	36	2598
ALTRUA 20 DR (downsize) S203	5000	360	3	34	0	39	2372

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ALTRUA 20 DR S202/S205	2000	63	0	11	2	15	859
ALTRUA 20 DR EL S208	3000	30	0	26	1	11	1326
INSIGNIA Ultra SR 1190 [4]	24000	2988	9	225	44	146	16775
INSIGNIA Ultra DR 1291 [4]	32000	5673	20	387	194	316	16305
INSIGNIA Entra SR 1195/1198 [4]	14000	1072	10	96	9	75	10750
INSIGNIA Entra DR 1294/1295 [4]	17000	2265	14	149	69	185	11280
INSIGNIA Plus DR 1297 [4]	27000	5912	20	279	133	262	15596

[1] Device malfunction consists of all U.S. confirmed malfunctions for a product/product grouping. These include confirmed malfunctions for advisory populations, as well as any other type of malfunction in which a device was returned and confirmed by laboratory analysis to have malfunctioned.. U.S. confirmed malfunction counts are reflected in U.S. survival probability.

[2] System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.

[3] Other consists of: patient death, electrive replacement, general product dissatisfaction, other observation/complication, unspecifed, or unknown.

[4] Counts consist of Boston Scientific and Intermedics co-branded pacemaker data.

ACUITY X4 Spiral L

Models 4677/4678

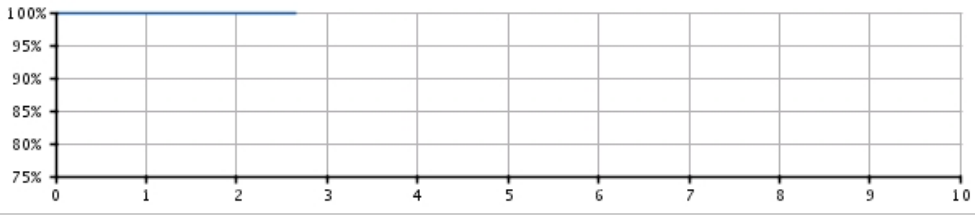
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 5,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 4
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 @ 32 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
Effective Sample Size	2131	397	214	–	–	–	–	–	–	–

ACUITY X4 Spiral L

Models 4677/4678

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACUITY X4 Spiral L Models 4677/4678

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	1	-	1
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

ACUITY X4 Spiral S

Models 4674/4675

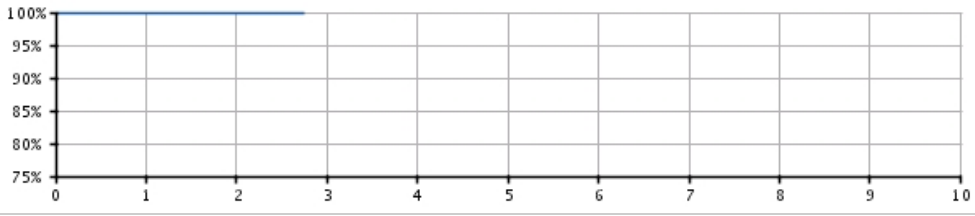
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 13,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 13,000

U.S. Chronic Lead Complications: 12
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 13000	99.88 (-0.1/+0.1)	99.88 (-0.1/+0.1)	99.88 @ 33 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
Effective Sample Size	4785	567	230	–	–	–	–	–	–	–

ACUITY X4 Spiral S

Models 4674/4675

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACUITY X4 Spiral S Models 4674/4675

Worldwide Distribution: 31,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	-	**0**
Insulation	-	-	**0**
Other	-	-	**0**
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

ACUITY X4 Straight

Models 4671/4672

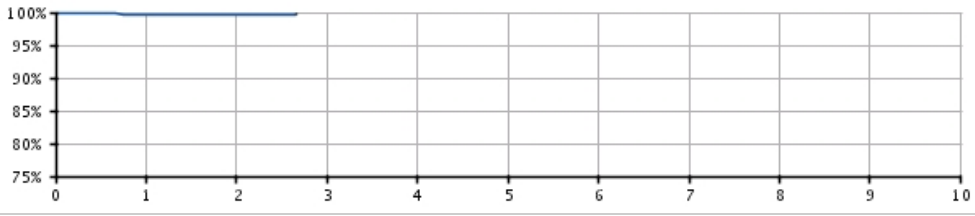
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 9,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 9,000

U.S. Chronic Lead Complications: 17
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 9000	99.73 (-0.2/+0.1)	99.73 (-0.2/+0.1)	99.73 @ 32 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
Effective Sample Size	3057	447	214	–	–	–	–	–	–	–

ACUITY X4 Straight

Models 4671/4672

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACUITY X4 Straight Models 4671/4672

Worldwide Distribution: 26,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	-	**0**
Insulation	-	-	**0**
Other	-	-	**0**
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

ACUITY Spiral

Models 4591/4592/4593

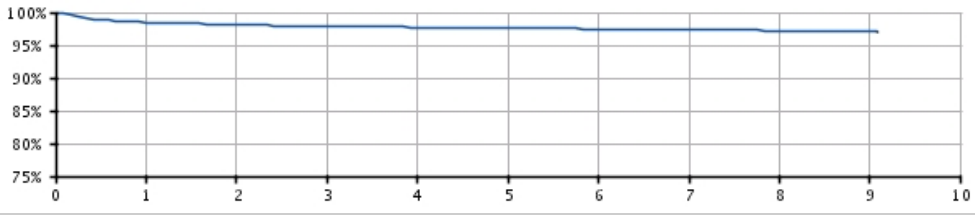
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 23,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 14,000

U.S. Chronic Lead Complications: 462
U.S. Malfunctions:8
Without Compromised Therapy:4
With Compromised Therapy:4

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	98.48 (-0.2/+0.2)	98.13 (-0.2/+0.2)	97.89 (-0.2/+0.2)	97.73 (-0.2/+0.2)	97.59 (-0.2/+0.2)	97.48 (-0.3/+0.2)	97.42 (-0.3/+0.2)	97.17 (-0.3/+0.3)	97.09 (-0.4/+0.3)	97.09 @ 109 mo. (-0.4/+0.3)
Effective Sample Size	19207	16526	13625	10543	7747	5375	3230	1562	320	239

ACUITY Spiral

Models 4591/4592/4593

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

ACUITY Spiral Models 4591/4592/4593

Worldwide Distribution: 44,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**3**	**4**
[27] Non-patterned, Conductor	1	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**1**	**1**	**2**
[28] Non-patterned, Insulation	1	1	
Other	**2**	**-**	**2**
[26] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**4**	**4**	**8**

More details about malfunctions

References cited in table above

ACUITY Spiral Longitude*

Models 4591/4592/4593

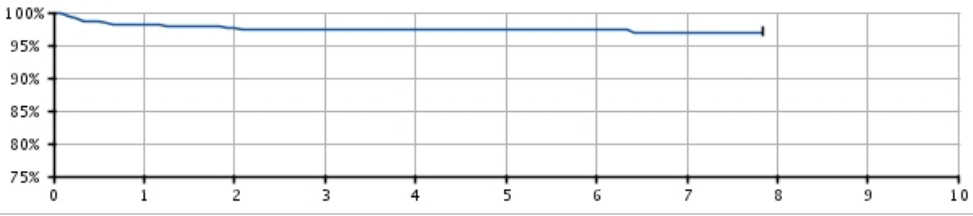
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 1383
Leads Active: 859
Cumulative Followup Months : 47,779

Chronic Lead Complications: 34
Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 1183	98.03 (-1.6/+1.6)	97.56 (-1.7/+1.7)	97.26 (-1.9/+1.9)	97.26 (-1.9/+1.9)	97.26 (-1.9/+1.9)	97.26 (-1.9/+1.9)	96.92 (-1.9/+3.8)	96.92 @ 94 mo. (-1.9/+3.8)	–	–
Effective Sample Size	1149	1000	867	676	527	360	188	56	–	–

ACUITY Steerable

Models 4554/4555/4556

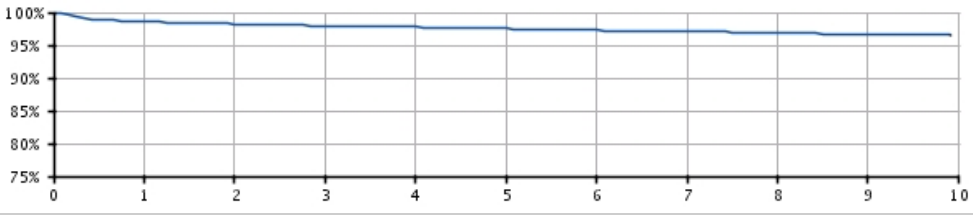
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 16,000

U.S. Chronic Lead Complications: 610
U.S. Malfunctions:33
Without Compromised Therapy:21
With Compromised Therapy:12

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 29000	98.59 (-0.1/+0.1)	98.23 (-0.2/+0.2)	97.97 (-0.2/+0.2)	97.76 (-0.2/+0.2)	97.51 (-0.2/+0.2)	97.27 (-0.2/+0.2)	97.08 (-0.3/+0.2)	96.90 (-0.3/+0.3)	96.65 (-0.3/+0.3)	96.46 (-0.4/+0.4)
Effective Sample Size	24323	21360	18160	14684	11584	8862	6333	4098	2060	454

ACUITY Steerable

Models 4554/4555/4556

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACUITY Steerable Models 4554/4555/4556

Worldwide Distribution: 64,000
Worldwide Confirmed Malfunctions: 57

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**13**	**36**	**49**
[27] Non-patterned, Conductor	8	9	
[34] Extracardiac fracture	5	27	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	**6**	**1**	**7**
[26] Non-patterned, Other	6	1	
WW Confirmed Malfunctions	**19**	**38**	**57**

More details about malfunctions

References cited in table above

EASYTRAK 3

Models 4522/4524/4525/4527/4548/
4549/4550

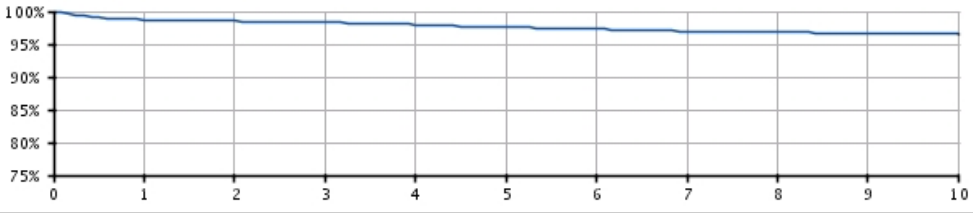
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 22,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 10,000

U.S. Chronic Lead Complications: 453
U.S. Malfunctions:30
Without Compromised Therapy:23
With Compromised Therapy:7

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	98.70 (-0.2/+0.1)	98.51 (-0.2/+0.2)	98.30 (-0.2/+0.2)	97.99 (-0.2/+0.2)	97.63 (-0.2/+0.2)	97.34 (-0.3/+0.2)	96.97 (-0.3/+0.3)	96.82 (-0.3/+0.3)	96.64 (-0.4/+0.3)	96.54 (-0.4/+0.3)
Effective Sample Size	18408	16212	13961	11587	9379	7577	6123	4876	3683	2719

EASYTRAK 3

Models 4522/4524/4525/4527/4548/
4549/4550

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

EASYTRAK 3
Models 4522/4524/4525/4527/4548/ 4549/4550

Worldwide Distribution: 43,000
Worldwide Confirmed Malfunctions: 49

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**10**	**34**	**44**
[27] Non-patterned, Conductor	6	5	
[34] Extracardiac fracture	4	29	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**3**	**1**	**4**
[28] Non-patterned, Insulation	3	1	
Other	**1**	**-**	**1**
[26] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**14**	**35**	**49**

More details about malfunctions

References cited in table above

EASYTRAK 2

Models 4515/4517/4518/4520/4542/
4543/4544

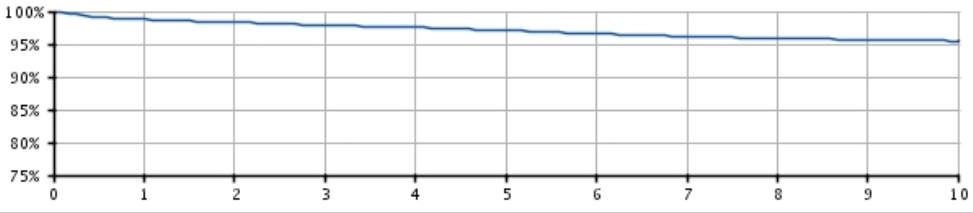
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 97,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 41,000

U.S. Chronic Lead Complications: 2,278
U.S. Malfunctions:366
Without Compromised Therapy:254
With Compromised Therapy:112

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 97000	98.77 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.90 (-0.1/+0.1)	97.54 (-0.1/+0.1)	97.09 (-0.1/+0.1)	96.59 (-0.1/+0.1)	96.17 (-0.2/+0.2)	95.88 (-0.2/+0.2)	95.69 (-0.2/+0.2)	95.49 (-0.2/+0.2)
Effective Sample Size	81491	71348	61246	51130	41985	33992	26839	20455	14862	10307

EASYTRAK 2

Models 4515/4517/4518/4520/4542/
4543/4544

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

EASYTRAK 2
Models 4515/4517/4518/4520/4542/ 4543/4544

Worldwide Distribution: 178,000
Worldwide Confirmed Malfunctions: 504

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**123**	**355**	**478**
[25] Conductor fracture	114	308	
[27] Non-patterned, Conductor	9	47	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**11**	**2**	**13**
[28] Non-patterned, Insulation	11	2	
Other	**8**	**5**	**13**
[26] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**142**	**362**	**504**

More details about malfunctions

References cited in table above

EASYTRAK

Models 4510/4511/4512/4513/4535/
4536/4537/4538

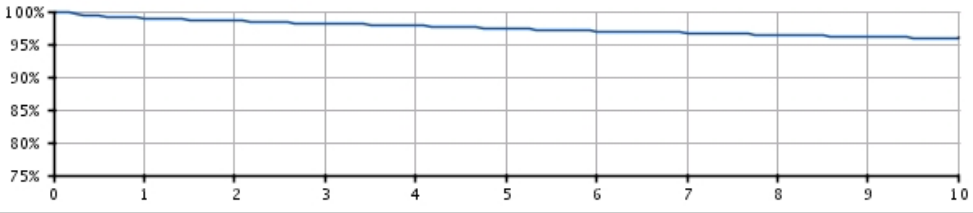
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 38,000
U.S. Approval Date: May 2002
U.S. Estimated Active Implants: 6,000

U.S. Chronic Lead Complications: 911
U.S. Malfunctions:24
Without Compromised Therapy:14
With Compromised Therapy:10

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 38000	98.94 (-0.1/+0.1)	98.57 (-0.1/+0.1)	98.15 (-0.2/+0.1)	97.84 (-0.2/+0.2)	97.36 (-0.2/+0.2)	97.00 (-0.2/+0.2)	96.74 (-0.2/+0.2)	96.36 (-0.3/+0.2)	96.11 (-0.3/+0.3)	95.94 (-0.3/+0.3)
Effective Sample Size	30530	26243	22509	19336	16498	14098	12091	10519	9250	8033

EASYTRAK

Models 4510/4511/4512/4513/4535/
4536/4537/4538

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

EASYTRAK
Models 4510/4511/4512/4513/4535/ 4536/4537/4538

Worldwide Distribution: 53,000
Worldwide Confirmed Malfunctions: 26

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**12**	**12**
[27] Non-patterned, Conductor	-	12	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**1**	**178**	**179**
[29] Unconfirmed Extrinsic	-	177	
[30] Inconclusive Extrinsic	1	1	
Insulation	**3**	**3**	**6**
[28] Non-patterned, Insulation	3	3	
Other	**6**	**-**	**-171**
Non-patterned	-	-	
[26] Non-patterned, Other	7	1	
WW Confirmed Malfunctions	**10**	**16**	**26**

More details about malfunctions

References cited in table above

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401/3501

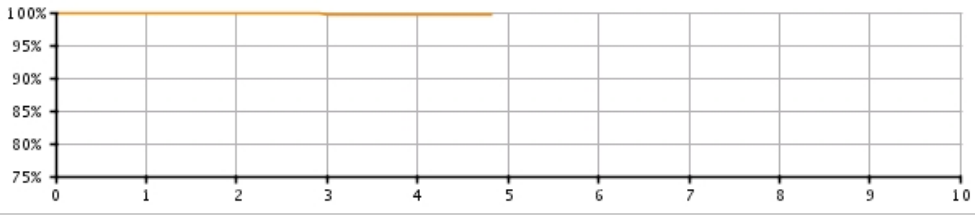
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 22,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 20,000

U.S. Chronic Lead Complications: 14
U.S. Malfunctions:1
Without Compromised Therapy:1
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	99.89 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.72 (-0.2/+0.1)	99.65 (-0.2/+0.1)	99.65 @ 58 mo. (-0.2/+0.1)	–	–	–	–	–
Effective Sample Size	13539	6994	2683	418	206	–	–	–	–	–

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401/3501

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

EMBLEM/Q-TRAK S-ICD Electrode Models 3010/3401/3501

Worldwide Distribution: 38,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**-**	**0**
Crimp/Weld/Bond	**-**	**3**	**3**
[37] Weld fracture	-	3	
Insulation	**-**	**-**	**0**
Other	**-**	**3**	**3**
[26] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**0**	**6**	**6**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation

Models 0658/0695/0696

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation Models 0658/0695/0696

Worldwide Distribution: 11,000

Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	-	**0**
Insulation	-	-	**0**
Other	-	-	**0**
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation

Models 0657/0692/0693

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE SG 4-FRONT Single Coil, Active Fixation Models 0657/0692/0693

Worldwide Distribution: 44,000

Worldwide Confirmed Malfunctions: 22

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**17**	**17**
[27] Non-patterned, Conductor	-	4	
[38] Conductor cable fracture	-	13	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**3**	**3**
[28] Non-patterned, Insulation	-	3	
Other	**-**	**2**	**2**
[26] Non-patterned, Other	-	2	
WW Confirmed Malfunctions	**0**	**22**	**22**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation

Models 0655/0685/0686

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE G 4-FRONT Dual Coil, Passive Fixation Models 0655/0685/0686

Worldwide Distribution: 1,000

Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	-	**0**
Insulation	-	-	**0**
Other	-	-	**0**
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation

Models 0654/0682/0683

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE SG 4-FRONT Single Coil, Passive Fixation Models 0654/0682/0683

Worldwide Distribution: 3,000

Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**1**	**1**
[38] Conductor cable fracture	-	1	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**-**	**0**
Other	**-**	**-**	**0**
WW Confirmed Malfunctions	**0**	**1**	**1**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation

Models 0275/0276/0295/0296

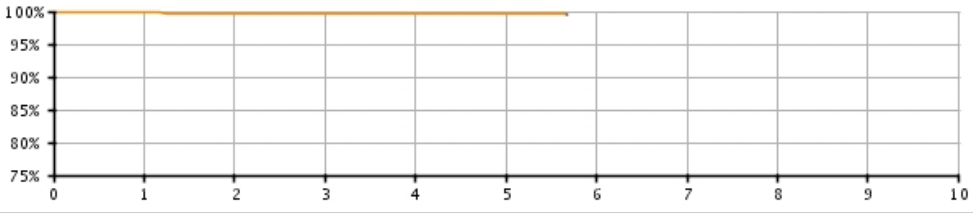
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 63,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 54,000

U.S. Chronic Lead Complications: 187
U.S. Malfunctions:14
Without Compromised Therapy:14
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 63000	99.78 (-0.0/+0.0)	99.69 (-0.1/+0.0)	99.63 (-0.1/+0.0)	99.59 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.52 @ 68 mo. (-0.1/+0.1)	–	–	–	–
Effective Sample Size	50374	38546	27135	16305	5907	386	–	–	–	–

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models 0275/0276/0295/0296

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation Models 0275/0276/0295/0296

Worldwide Distribution: 102,000

Worldwide Confirmed Malfunctions: 43

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**3**	**3**
[27] Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**7**	**31**	**38**
[28] Non-patterned, Insulation	7	31	
Other	**2**	**-**	**2**
[26] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**9**	**34**	**43**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation Longitude*

Models 0275/0276/0295/0296

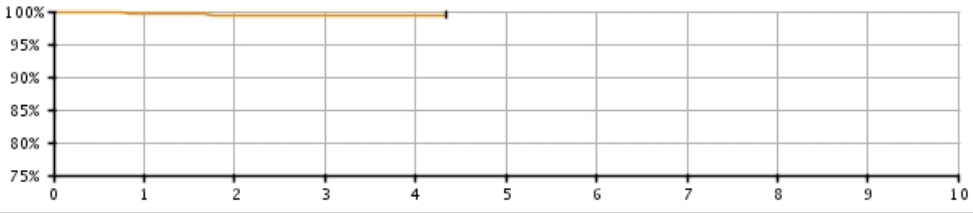
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 850
Leads Active: 612
Cumulative Followup Months : 27,491

Chronic Lead Complications: 3
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 850	99.75 (-1.6/+1.6)	99.46 (-1.7/+1.7)	99.29 (-1.9/+1.9)	99.29 (-1.9/+2.0)	99.29 @ 52 mo. (-1.9/+3.8)	–	–	–	–	–
Effective Sample Size	744	657	544	99	50	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation

Models 0265/0266/0285/0286

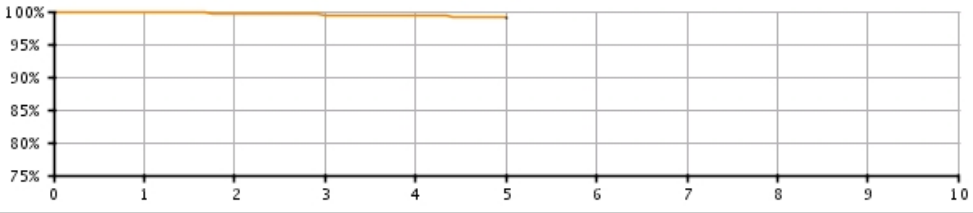
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 2,000

U.S. Chronic Lead Complications: 12
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.76 (-0.3/+0.1)	99.65 (-0.4/+0.2)	99.49 (-0.5/+0.2)	99.37 (-0.6/+0.3)	99.13 (-0.9/+0.4)	–	–	–	–	–
Registered Implants: 3000										
Effective Sample Size	2167	1640	1094	580	201	–	–	–	–	–

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models 0265/0266/0285/0286

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation Models 0265/0266/0285/0286

Worldwide Distribution: 9,000

Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	-	**0**
Insulation	-	-	**0**
Other	-	-	**0**
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Single Coil, Active Fixation

Models 0292/0293

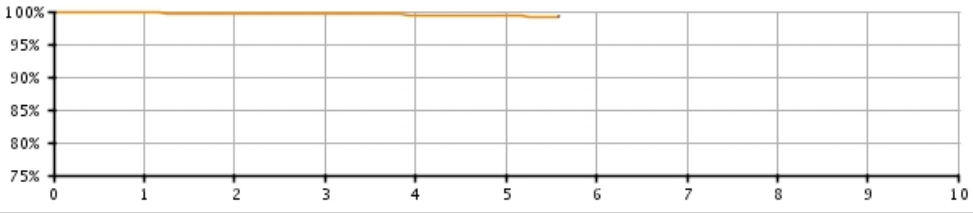
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 81,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 74,000

U.S. Chronic Lead Complications: 225
U.S. Malfunctions:14
Without Compromised Therapy:1
With Compromised Therapy:13

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 81000	99.78 (-0.0/+0.0)	99.69 (-0.0/+0.0)	99.61 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.37 (-0.2/+0.1)	99.25 @ 67 mo. (-0.3/+0.2)	–	–	–	–
Effective Sample Size	56105	35936	20136	9276	2545	378	–	–	–	–

ENDOTAK RELIANCE 4-Site
Single Coil, Active Fixation

Models 0292/0293

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation Models 0292/0293

Worldwide Distribution: 129,000

Worldwide Confirmed Malfunctions: 34

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**2**	**2**
[24] Conductor fracture	-	1	
[27] Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**26**	**28**
[28] Non-patterned, Insulation	2	26	
Other	**-**	**4**	**4**
[26] Non-patterned, Other	-	4	
WW Confirmed Malfunctions	**2**	**32**	**34**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Single Coil, Active Fixation Longitude*

Models 0292/0293

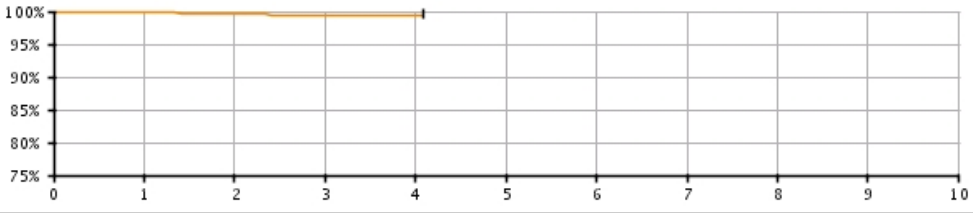
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 1104
Leads Active: 884
Cumulative Followup Months : 36,380

U.S. Chronic Lead Complications: 5
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 1104	99.89 (-1.6/+1.6)	99.53 (-1.7/+1.7)	99.39 (-1.9/+1.9)	99.39 (-1.9/+3.8)	99.39 @ 49 mo. (-1.9/+3.8)	–	–	–	–	–
Effective Sample Size	854	758	642	85	63	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Single Coil, Passive Fixation

Models 0282/0283

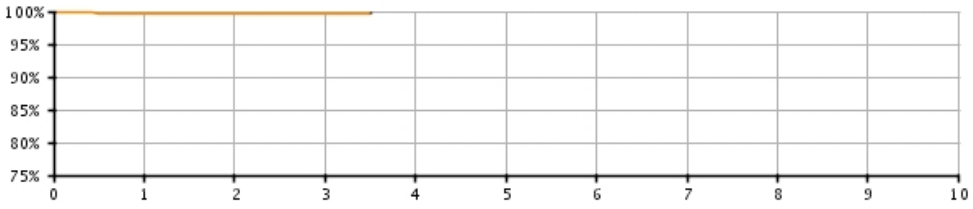
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 4
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	99.72 (-0.5/+0.2)	99.72 (-0.5/+0.2)	99.72 (-0.5/+0.2)	99.72 @ 42 mo. (-0.5/+0.2)	–	–	–	–	–	–
Effective Sample Size	1038	607	291	206	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Single Coil, Passive Fixation

Models 0282/0283

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation Models 0282/0283

Worldwide Distribution: 5,000

Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	-	**0**
Insulation	-	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	-	-	**0**
WW Confirmed Malfunctions	**0**	**1**	**1**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation

Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

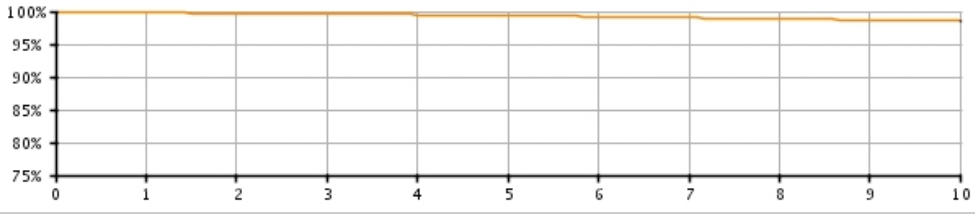
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 287,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 131,000

U.S. Chronic Lead Complications: 2,045
U.S. Malfunctions:304
Without Compromised Therapy:193
With Compromised Therapy:111

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 286000	99.80 (-0.0/+0.0)	99.70 (-0.0/+0.0)	99.61 (-0.0/+0.0)	99.50 (-0.0/+0.0)	99.37 (-0.0/+0.0)	99.22 (-0.0/+0.0)	99.03 (-0.0/+0.0)	98.87 (-0.1/+0.1)	98.70 (-0.1/+0.1)	98.52 (-0.1/+0.1)
Effective Sample Size	251954	224500	199760	177136	155959	132767	106129	82556	60196	41993

ENDOTAK RELIANCE
Dual Coil, Active Fixation

Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE
Dual Coil, Active Fixation
Models 0157/0158/0159/0164/0165/ 0166/0167/0184/0185/0186/ 0187

Worldwide Distribution: 375,000
Worldwide Confirmed Malfunctions: 474

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**133**	**135**
[24] Conductor fracture	-	89	
[27] Non-patterned, Conductor	2	44	
Crimp/Weld/Bond	**6**	**1**	**7**
[5] Seal rings	3	1	
[31] Non-patterned, Crimp, Weld, Bond	3	-	
Insulation	**147**	**136**	**283**
[28] Non-patterned, Insulation	147	136	
Other	**29**	**20**	**49**
[26] Non-patterned, Other	29	20	
WW Confirmed Malfunctions	**184**	**290**	**474**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation Longitude*

Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

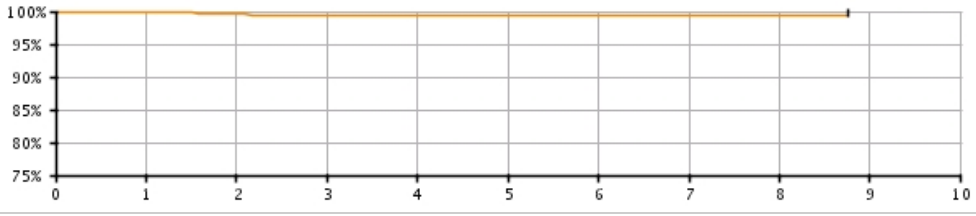
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 741
Leads Active: 383
Cumulative Followup Months : 26,080

Chronic Lead Complications: 5
Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 741	100 (-1.6/+1.6)	99.67 (-1.7/+1.7)	99.49 (-1.9/+1.9)	99.49 (-1.9/+1.9)	99.49 (-1.9/+1.9)	99.49 (-1.9/+3.8)	99.49 (-1.9/+3.8)	99.49 (-1.9/+3.8)	99.49 @ 105 mo. (-1.9/+3.8)	–
Effective Sample Size	645	572	508	444	379	309	203	78	51	–

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149/0174/0175/
0176/0177

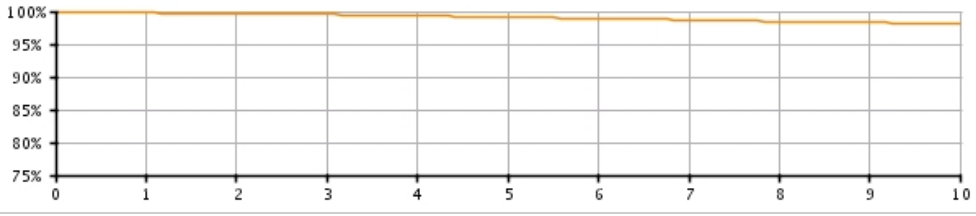
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 47,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 16,000

U.S. Chronic Lead Complications: 522
U.S. Malfunctions:41
Without Compromised Therapy:31
With Compromised Therapy:10

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 46000	99.77 (-0.0/+0.0)	99.68 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.34 (-0.1/+0.1)	99.14 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.69 (-0.1/+0.1)	98.46 (-0.2/+0.1)	98.27 (-0.2/+0.2)	98.08 (-0.2/+0.2)
Effective Sample Size	40595	36189	32195	28554	25112	21854	18706	15874	13300	10980

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149/0174/0175/
0176/0177

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE
Dual Coil, Passive Fixation
Models 0147/0148/0149/0174/0175/ 0176/0177

Worldwide Distribution: 109,000

Worldwide Confirmed Malfunctions: 132

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**31**	**31**
[24] Conductor fracture	-	18	
[27] Non-patterned, Conductor	-	13	
Crimp/Weld/Bond	**-**	**3**	**3**
[36] Conductor connection	-	3	
Insulation	**38**	**48**	**86**
[28] Non-patterned, Insulation	38	48	
Other	**8**	**4**	**12**
[6] Manufacturing material	-	1	
[26] Non-patterned, Other	8	3	
WW Confirmed Malfunctions	**46**	**86**	**132**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Active Fixation

Models 0137/0138/0160/0161/0162/
0180/0181/0182

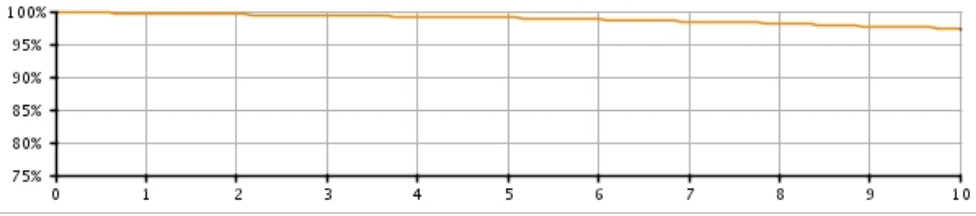
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 32,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 22,000

U.S. Chronic Lead Complications: 243
U.S. Malfunctions:62
Without Compromised Therapy:42
With Compromised Therapy:20

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 32000	99.69 (-0.1/+0.1)	99.53 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.22 (-0.1/+0.1)	99.04 (-0.1/+0.1)	98.79 (-0.2/+0.1)	98.46 (-0.2/+0.2)	98.14 (-0.3/+0.2)	97.63 (-0.4/+0.4)	97.37 (-0.6/+0.5)
Effective Sample Size	27636	23853	19977	16407	13170	9566	5722	3488	1821	840

ENDOTAK RELIANCE
Single Coil, Active Fixation

Models 0137/0138/0160/0161/0162/
0180/0181/0182

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE
Single Coil, Active Fixation
Models 0137/0138/0160/0161/0162/ 0180/0181/0182

Worldwide Distribution: 70,000

Worldwide Confirmed Malfunctions: 161

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**63**	**63**
[24] Conductor fracture	-	54	
[27] Non-patterned, Conductor	-	9	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**48**	**37**	**85**
[28] Non-patterned, Insulation	48	37	
Other	**8**	**5**	**13**
[26] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**56**	**105**	**161**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Passive Fixation

Models 0127/0128/0170/0171/0172/
0173

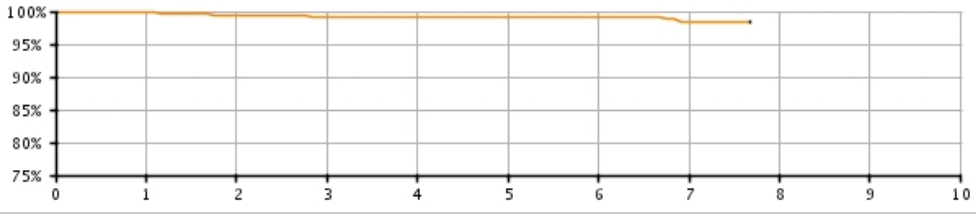
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 18
U.S. Malfunctions:1
Without Compromised Therapy:0
With Compromised Therapy:1

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	99.76 (-0.4/+0.2)	99.39 (-0.6/+0.3)	99.20 (-0.7/+0.4)	99.09 (-0.7/+0.4)	99.09 (-0.7/+0.4)	99.09 (-0.7/+0.4)	98.40 (-1.5/+0.8)	98.40 @ 92 mo. (-1.5/+0.8)	–	–
Effective Sample Size	1495	1236	963	763	559	384	263	205	–	–

ENDOTAK RELIANCE
Single Coil, Passive Fixation

Models 0127/0128/0170/0171/0172/
0173

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE
Single Coil, Passive Fixation
Models 0127/0128/0170/0171/0172/ 0173

Worldwide Distribution: 8,000

Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**5**	**5**
[24] Conductor fracture	-	3	
[27] Non-patterned, Conductor	-	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**6**	**4**	**10**
[28] Non-patterned, Insulation	6	4	
Other	**1**	**-**	**1**
[26] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**7**	**9**	**16**

More details about malfunctions

References cited in table above

ENDOTAK ENDURANCE EZ
Active Fixation

Models 0154/0155/0156

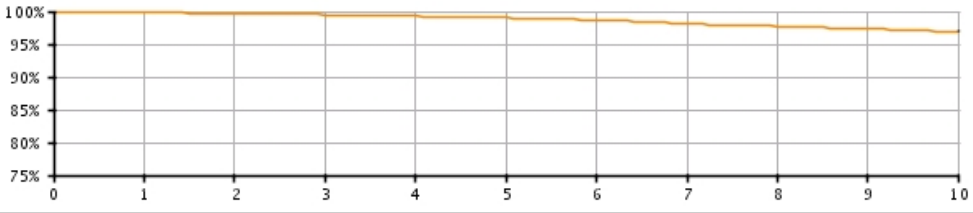
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: June 1999
U.S. Estimated Active Implants: 6,000

U.S. Chronic Lead Complications: 596
U.S. Malfunctions:26
Without Compromised Therapy:11
With Compromised Therapy:15

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.66 (-0.2/+0.2)	98.14 (-0.2/+0.2)	97.73 (-0.3/+0.2)	97.31 (-0.3/+0.3)	96.96 (-0.3/+0.3)
Registered Implants: 29000										
Effective Sample Size	24452	21792	19398	17263	15330	13599	12053	10711	9490	8401

ENDOTAK ENDURANCE Rx
Passive Fixation Steroid Eluting

Models 0144/0145/0146

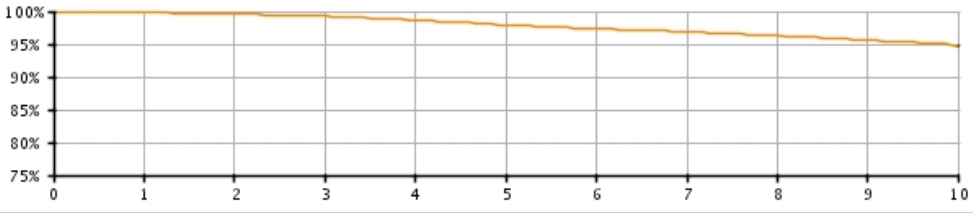
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 18,000
U.S. Approval Date: January 1999
U.S. Estimated Active Implants: 4,000

U.S. Chronic Lead Complications: 696
U.S. Malfunctions:30
Without Compromised Therapy:8
With Compromised Therapy:22

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.26 (-0.2/+0.1)	98.65 (-0.2/+0.2)	97.92 (-0.3/+0.2)	97.39 (-0.3/+0.3)	96.85 (-0.3/+0.3)	96.26 (-0.4/+0.4)	95.65 (-0.4/+0.4)	94.69 (-0.5/+0.5)
Registered Implants: 18000										
Effective Sample Size	15628	13937	12418	10989	9679	8564	7597	6723	5920	5203

INGEVITY Atrial J Passive Fixation

Models 7635/7636/7735/7736

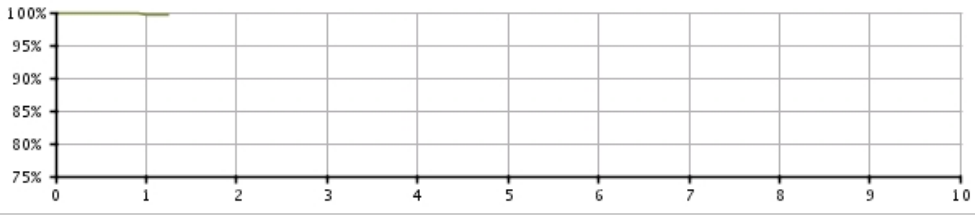
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 4,000
U.S. Approval Date: April 2006
U.S. Estimated Active Implants: 4,000

U.S. Chronic Lead Complications: 7
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	99.67 (-0.4/+0.2)	99.67 @ 15 mo. (-0.4/+0.2)	–	–	–	–	–	–	–	–
Effective Sample Size	909	343	–	–	–	–	–	–	–	–

INGEVITY Atrial J Passive Fixation

Models 7635/7636/7735/7736

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INGEVITY Atrial J Passive Fixation Models 7635/7636/7735/7736

Worldwide Distribution: 36,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	-	**0**
Insulation	-	-	**0**
Other	-	-	**0**
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

INGEVITY Positive Fixation

Models 7640/7641/7642/7740/7741/
7742

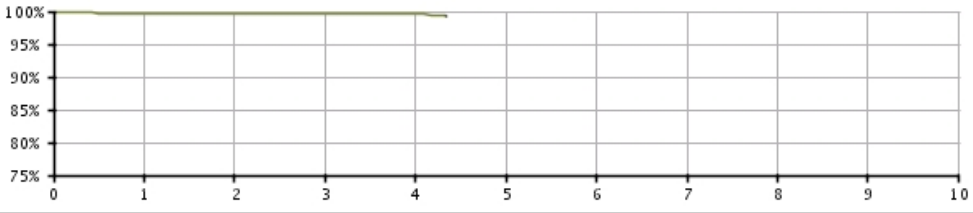
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 127,000
U.S. Approval Date: April 2016
U.S. Estimated Active Implants: 122,000

U.S. Chronic Lead Complications: 276
U.S. Malfunctions:24
Without Compromised Therapy:10
With Compromised Therapy:14

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 127000	99.64 (-0.0/+0.0)	99.64 (-0.0/+0.0)	99.64 (-0.0/+0.0)	99.64 (-0.0/+0.0)	99.37 @ 52 mo. (-0.8/+0.4)	–	–	–	–	–
Effective Sample Size	31620	922	817	488	226	–	–	–	–	–

INGEVITY Positive Fixation

Models 7640/7641/7642/7740/7741/
7742

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INGEVITY Positive Fixation Models 7640/7641/7642/7740/7741/ 7742

Worldwide Distribution: 362,000
Worldwide Confirmed Malfunctions: 53

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**22**	**28**	**50**
[27] Non-patterned, Conductor	17	26	
[39] Inner conductor break	5	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	**1**	**1**	**2**
[26] Non-patterned, Other	1	1	
WW Confirmed Malfunctions	**23**	**30**	**53**

More details about malfunctions

References cited in table above

INGEVITY Passive Fixation

Models 7631/7632/7731/7732

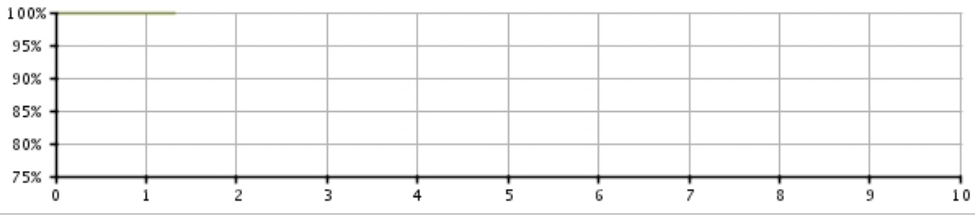
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 7,000
U.S. Approval Date: April 2016
U.S. Estimated Active Implants: 6,000

U.S. Chronic Lead Complications: 4
U.S. Malfunctions:2
Without Compromised Therapy:2
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	99.87 (-0.2/+0.1)	99.87 @ 16 mo. (-0.2/+0.1)	–	–	–	–	–	–	–	–
Effective Sample Size	1744	358	–	–	–	–	–	–	–	–

INGEVITY Passive Fixation

Models 7631/7632/7731/7732

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INGEVITY Passive Fixation Models 7631/7632/7731/7732

Worldwide Distribution: 42,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**4**	**4**
[27] Non-patterned, Conductor	-	4	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**-**	**0**
Other	**-**	**1**	**1**
[26] Non-patterned, Other	-	1	
WW Confirmed Malfunctions	**0**	**5**	**5**

More details about malfunctions

References cited in table above

FLEXTEND 2 Active Fixation

Models 4095/4096/4097

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FLEXTEND 2 Active Fixation Models 4095/4096/4097

Worldwide Distribution: 185,000
Worldwide Confirmed Malfunctions: 116

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**6**	**32**	**38**
[7] Lead conductor	2	18	
[32] Conductor damage	4	14	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**54**	**10**	**64**
[2] Inner insulation abrasion	4	1	
[28] Non-patterned, Insulation	3	-	
[33] Insulation damage	47	9	
Other	**14**	**-**	**14**
[26] Non-patterned, Other	14	-	
WW Confirmed Malfunctions	**74**	**42**	**116**

More details about malfunctions

References cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

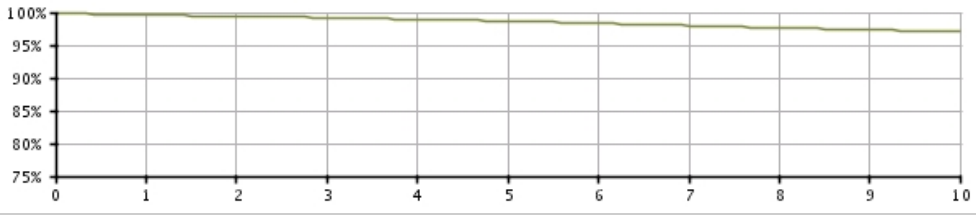
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 235,000
U.S. Approval Date: February 2002
U.S. Estimated Active Implants: 93,000

U.S. Chronic Lead Complications: 3,471
U.S. Malfunctions:334
Without Compromised Therapy:135
With Compromised Therapy:199

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 235000	99.60 (-0.0/+0.0)	99.40 (-0.0/+0.0)	99.20 (-0.0/+0.0)	98.94 (-0.0/+0.0)	98.67 (-0.1/+0.1)	98.34 (-0.1/+0.1)	98.00 (-0.1/+0.1)	97.65 (-0.1/+0.1)	97.33 (-0.1/+0.1)	97.09 (-0.1/+0.1)
Effective Sample Size	201609	177080	154142	133183	114392	97393	81827	67420	54950	44531

FLEXTEND Active Fixation

Models 4086/4087/4088

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FLEXTEND Active Fixation Models 4086/4087/4088

Worldwide Distribution: 290,000
Worldwide Confirmed Malfunctions: 359

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**18**	**174**	**192**
[7] Lead conductor	11	82	
[27] Non-patterned, Conductor	-	7	
[32] Conductor damage	7	85	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**109**	**35**	**144**
[2] Inner insulation abrasion	19	8	
[28] Non-patterned, Insulation	9	1	
[33] Insulation damage	81	26	
Other	**17**	**6**	**23**
[26] Non-patterned, Other	17	6	
WW Confirmed Malfunctions	**144**	**215**	**359**

More details about malfunctions

References cited in table above

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane)

Models 4463/4464/4465/4469/4470/ 4471

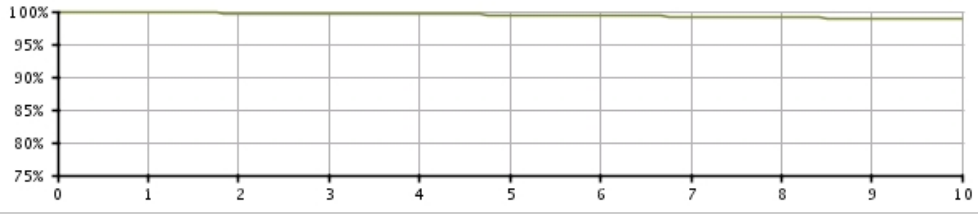
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 461,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 252,000

U.S. Chronic Lead Complications: 2,569
U.S. Malfunctions:139
Without Compromised Therapy:32
With Compromised Therapy:107

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.0/+0.0)	99.74 (-0.0/+0.0)	99.67 (-0.0/+0.0)	99.57 (-0.0/+0.0)	99.47 (-0.0/+0.0)	99.35 (-0.0/+0.0)	99.20 (-0.0/+0.0)	99.07 (-0.0/+0.0)	98.92 (-0.1/+0.0)	98.78 (-0.1/+0.1)
Registered Implants: 460000										
Effective Sample Size	397825	341152	287619	239940	197989	160896	127905	98522	73507	54621

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane)

Models 4463/4464/4465/4469/4470/ 4471

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) Models 4463/4464/4465/4469/4470/ 4471

Worldwide Distribution: 712,000

Worldwide Confirmed Malfunctions: 169

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**16**	**121**	**137**
[7] Lead conductor	8	56	
[27] Non-patterned, Conductor	1	5	
[32] Conductor damage	7	60	
Crimp/Weld/Bond	**1**	**2**	**3**
[23] Terminal weld	-	1	
[31] Non-patterned, Crimp, Weld, Bond	1	1	
Insulation	**12**	**6**	**18**
[33] Insulation damage	12	6	
Other	**8**	**2**	**10**
[26] Non-patterned, Other	8	2	
WW Confirmed Malfunctions	**37**	**132**	**169**

More details about malfunctions

References cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude*

Models 4463/4464/4465/4469/4470/
4471

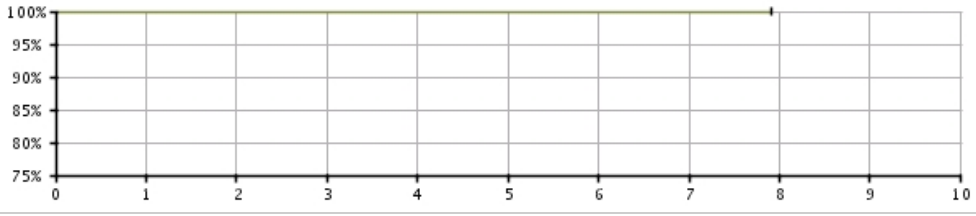
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 924
Leads Active: 652
Cumulative Followup Months : 31,134

Chronic Lead Complications: 2
Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 924	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.5)	99.77 @ 95 mo. (-1.9/+3.4)	–	–
Effective Sample Size	779	689	584	306	233	175	112	57	–	–

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

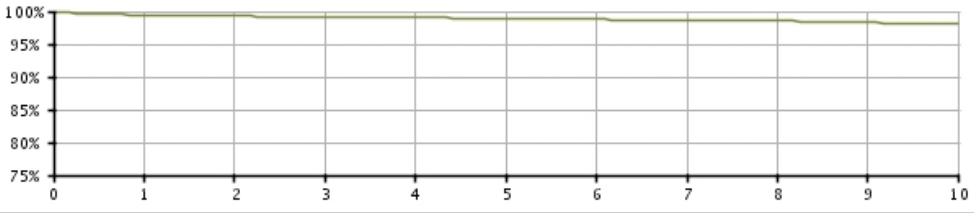
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 62,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 30,000

U.S. Chronic Lead Complications: 652
U.S. Malfunctions:26
Without Compromised Therapy:19
With Compromised Therapy:7

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.44 (-0.1/+0.1)	99.28 (-0.1/+0.1)	99.15 (-0.1/+0.1)	99.04 (-0.1/+0.1)	98.94 (-0.1/+0.1)	98.79 (-0.1/+0.1)	98.64 (-0.1/+0.1)	98.52 (-0.1/+0.1)	98.26 (-0.2/+0.1)	98.18 (-0.2/+0.2)
Registered Implants: 62000										
Effective Sample Size	53089	45974	39099	32960	27443	22571	18237	14469	11139	8557

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)
Models 4477/4478/4479/4480

Worldwide Distribution: 299,000

Worldwide Confirmed Malfunctions: 52

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**4**	**10**	**14**
[7] Lead conductor	1	3	
[32] Conductor damage	3	7	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[33] Insulation damage	-	1	
Other	**32**	**4**	**36**
[21] J-shape	30	4	
[26] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**37**	**15**	**52**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

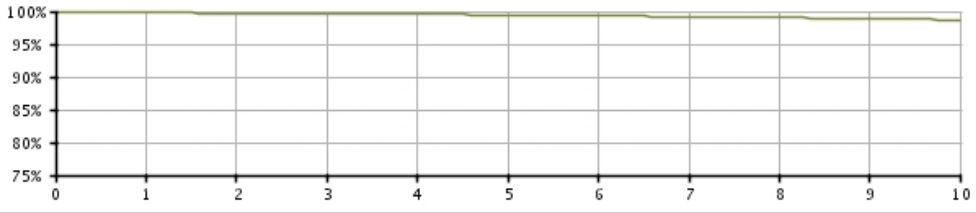
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 189,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 85,000

U.S. Chronic Lead Complications: 1,161
U.S. Malfunctions:43
Without Compromised Therapy:5
With Compromised Therapy:38

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.64 (-0.0/+0.0)	99.56 (-0.0/+0.0)	99.46 (-0.0/+0.0)	99.35 (-0.0/+0.0)	99.19 (-0.1/+0.1)	99.05 (-0.1/+0.1)	98.84 (-0.1/+0.1)	98.72 (-0.1/+0.1)
Registered Implants: 189000										
Effective Sample Size	162577	140854	119736	100827	84180	69602	56655	45198	35098	27288

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) Models 4452/4453/4456/4457

Worldwide Distribution: 527,000

Worldwide Confirmed Malfunctions: 62

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**46**	**47**
[7] Lead conductor	-	15	
[27] Non-patterned, Conductor	-	2	
[32] Conductor damage	1	29	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**7**	**9**
[33] Insulation damage	2	7	
Other	**4**	**-**	**4**
[26] Non-patterned, Other	4	-	
WW Confirmed Malfunctions	**7**	**55**	**62**

More details about malfunctions

References cited in table above

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone)

Models 4466/4467/4468/4472/4473/ 4474

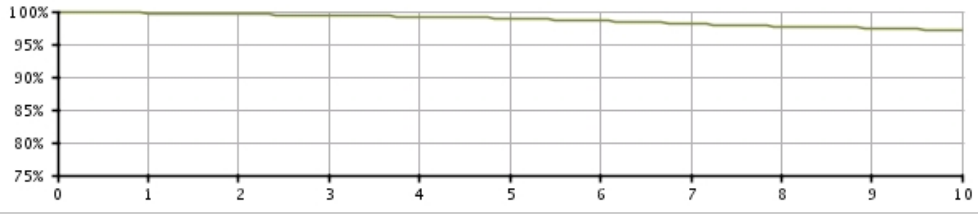
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 52,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 23,000

U.S. Chronic Lead Complications: 636
U.S. Malfunctions:125
Without Compromised Therapy:23
With Compromised Therapy:102

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 52000	99.74 (-0.0/+0.0)	99.58 (-0.1/+0.1)	99.40 (-0.1/+0.1)	99.20 (-0.1/+0.1)	98.92 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.10 (-0.2/+0.2)	97.69 (-0.2/+0.2)	97.45 (-0.2/+0.2)	97.16 (-0.2/+0.2)
Effective Sample Size	45667	39912	34407	29445	24880	20791	17059	13713	10896	8608

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone)

Models 4466/4467/4468/4472/4473/ 4474

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone) Models 4466/4467/4468/4472/4473/ 4474

Worldwide Distribution: 141,000

Worldwide Confirmed Malfunctions: 164

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**11**	**124**	**135**
[7] Lead conductor	4	74	
[27] Non-patterned, Conductor	-	2	
[32] Conductor damage	7	45	
[35] Lead conductor	-	3	
Crimp/Weld/Bond	**1**	**-**	**1**
[31] Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	**9**	**9**	**18**
[28] Non-patterned, Insulation	2	-	
[33] Insulation damage	7	9	
Other	**6**	**4**	**10**
[26] Non-patterned, Other	6	4	
WW Confirmed Malfunctions	**27**	**137**	**164**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

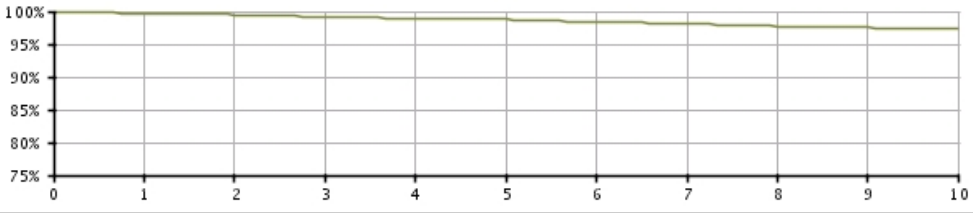
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 15,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 193
U.S. Malfunctions:24
Without Compromised Therapy:0
With Compromised Therapy:24

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 15000	99.67 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.19 (-0.2/+0.1)	98.93 (-0.2/+0.2)	98.77 (-0.2/+0.2)	98.45 (-0.3/+0.2)	98.08 (-0.3/+0.3)	97.75 (-0.4/+0.3)	97.51 (-0.4/+0.3)	97.39 (-0.4/+0.4)
Effective Sample Size	12465	10962	9547	8226	7106	5996	5023	4158	3435	2862

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) Models 4454/4455/4458/4459

Worldwide Distribution: 104,000

Worldwide Confirmed Malfunctions: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**45**	**45**
[7] Lead conductor	-	17	
[32] Conductor damage	-	28	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**4**	**6**
[33] Insulation damage	2	4	
Other	**-**	**3**	**3**
[26] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**2**	**52**	**54**

More details about malfunctions

References cited in table above

FINELINE EZ Positive Fixation

Models 4460/4461/4462

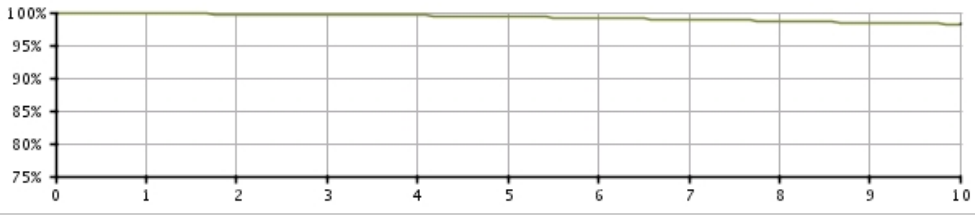
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 24,000
U.S. Approval Date: July 1999
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 300
U.S. Malfunctions:10
Without Compromised Therapy:1
With Compromised Therapy:9

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 24000	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.64 (-0.1/+0.1)	99.53 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.14 (-0.2/+0.1)	98.93 (-0.2/+0.2)	98.69 (-0.2/+0.2)	98.44 (-0.2/+0.2)	98.22 (-0.3/+0.2)
Effective Sample Size	20916	18713	16693	14869	13218	11627	10248	9035	7926	6992

SELUTE PICOTIP
Passive Fixation

Models 4030/4031/4032/4033/4034/
4035

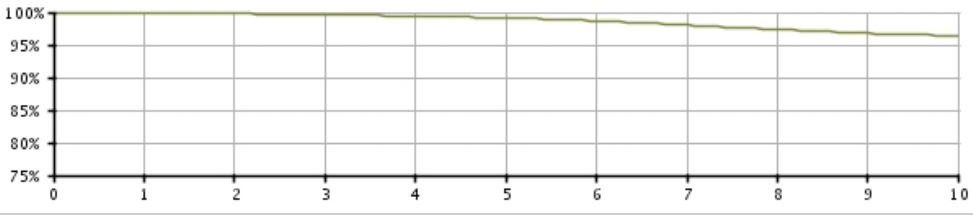
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 58,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 12,000

U.S. Chronic Lead Complications: 1,132
U.S. Malfunctions:36

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.86 (-0.0/+0.0)	99.78 (-0.0/+0.0)	99.64 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.15 (-0.1/+0.1)	98.67 (-0.1/+0.1)	98.05 (-0.2/+0.1)	97.37 (-0.2/+0.2)	96.78 (-0.2/+0.2)	96.39 (-0.2/+0.2)
Registered Implants: 58000										
Effective Sample Size	49276	43964	39175	34802	30799	27091	23775	20902	18271	15911

SELUTE PICOTIP Atrial J

Models 4040/4041/4042/4043/4044/
4045/4063/4064

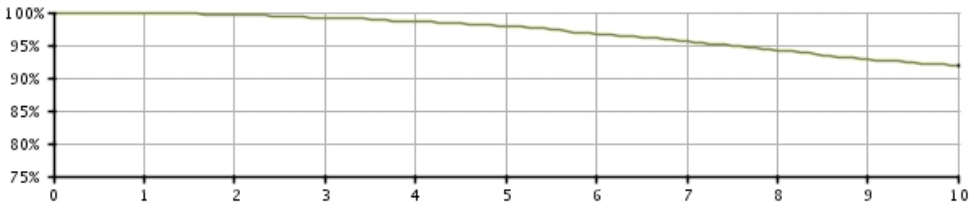
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 10,000
U.S. Approval Date: May 2000
U.S. Estimated Active Implants: 2,000

U.S. Chronic Lead Complications: 442
U.S. Malfunctions:22

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 10000	99.87 (-0.1/+0.1)	99.65 (-0.2/+0.1)	99.19 (-0.2/+0.2)	98.61 (-0.3/+0.2)	97.89 (-0.4/+0.3)	96.67 (-0.5/+0.4)	95.57 (-0.6/+0.5)	94.22 (-0.7/+0.6)	92.87 (-0.8/+0.7)	91.83 (-0.9/+0.8)
Effective Sample Size	8577	7643	6793	6022	5318	4666	4029	3477	2978	2544

SWEET PICOTIP Rx
Positive Fixation

Models 4050/4051/4052/4053/4054/
4055

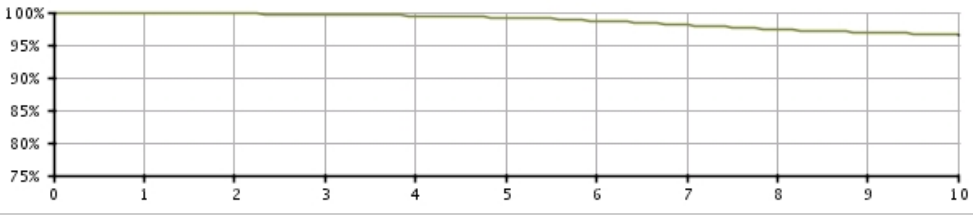
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 41,000
U.S. Approval Date: April 1999
U.S. Estimated Active Implants: 11,000

U.S. Chronic Lead Complications: 708
U.S. Malfunctions:58

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 41000	99.91 (-0.0/+0.0)	99.81 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.68 (-0.2/+0.1)	98.05 (-0.2/+0.2)	97.43 (-0.2/+0.2)	96.91 (-0.3/+0.2)	96.56 (-0.3/+0.3)
Effective Sample Size	35767	31935	28498	25356	22465	19812	17401	15251	13157	10970

SWEET TIP
Positive Fixation

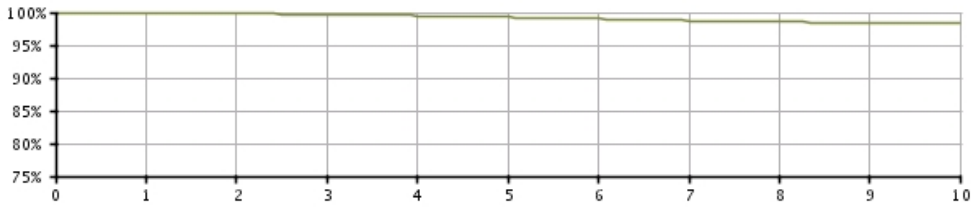
Models 4165/4168/4169/4268/4269

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 89,000
U.S. Estimated Active Implants: 15,000
U.S. Chronic Lead Complications: 982
U.S. Malfunctions:162

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 89000	99.88 (-0.0/+0.0)	99.79 (-0.0/+0.0)	99.68 (-0.0/+0.0)	99.50 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.72 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.41 (-0.1/+0.1)	98.28 (-0.1/+0.1)
Effective Sample Size	77717	69455	62066	55311	49106	43279	38075	33559	29650	26153

SWEET TIP RX
Positive Fixation

Models 4143/4144/4145/4243/4244/
4245

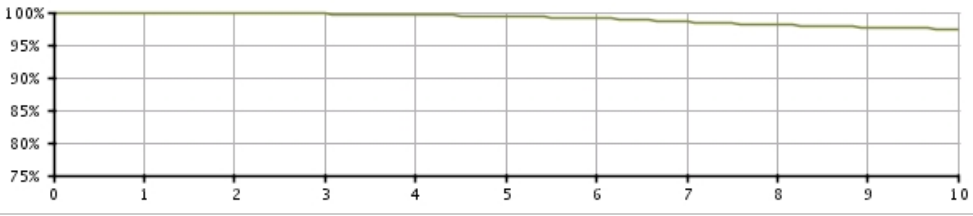
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 34,000
U.S. Approval Date: October 1998
U.S. Estimated Active Implants: 7,000

U.S. Chronic Lead Complications: 512
U.S. Malfunctions:28

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.90 (-0.0/+0.0)	99.82 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	99.10 (-0.1/+0.1)	98.56 (-0.2/+0.2)	98.08 (-0.2/+0.2)	97.73 (-0.2/+0.2)	97.40 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29683	26537	23706	21102	18667	16397	14400	12642	11113	9543

Confirmed Malfunction Details: Leads

References

Descriptions listed below provide an overview of the clinical observations and/or analysis findings associated with each confirmed lead malfunction pattern listed in this report.

All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, changes have been or will be implemented in response to identified malfunction patterns. "Improvements implemented" may include product design changes in existing or subsequent generations, manufacturing process modifications, educational communications, labeling changes, etc. Improvement implementation may vary by geography due to various factors, including regulatory review timing, and may not completely mitigate or eliminate the potential for additional malfunctions.

1. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
2. **Inner insulation abrasion**— Loss of capture, decreasing impedance, increased pacing thresholds, noisy signals, oversensing. Abrasion of inner insulation.
3. **Terminal leg insulation**— Loss of sensing, loss of pacing, loss of defibrillation therapy. Abraded insulation on terminal leg portion of lead due to lead-on-lead or lead-on-can contact. Improvement implemented.
4. **Lead body**— Insulation abrasion due to lead-on-lead or lead-on-can contact combined with damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
5. **Seal rings**— Insertion difficulty at implant, difficulty removing lead from header post-implant. Proximal silicone seal rings not fully adhered to lead terminal. Improvement implemented.
6. **Manufacturing material**— Loss of sensing, loss of pacing, noisy signals. Manufacturing material embedded in lead body.
7. **Lead conductor**— Loss of capture, inability to deliver therapy. Fatigue of lead conductor due to repeated flexing.
8. **Lead body**— Lead fracture, inappropriate shocks, oversensing. Insulation damage resulting from implant stresses or manufacturing variability.
9. **Lead conductor**— Loss of sensing, loss of pacing. Physical damage to lead body due to repeated flexing.
10. **Lead connector**— Insulation damage resulting from bending or tension at the terminal connector. May lead to inappropriate shocks, oversensing.
11. **Lead conductor**— Physical damage to lead conductor, inappropriate shocks, oversensing. Displacement of yoke component may lead to fatigue of high-voltage lead conductor. Improvement implemented.
12. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
13. **Serial number label**— Loss of sensing, loss of pacing. Sharp edge in serial number label resulting in breach in outer lead insulation. Improvement implemented.
14. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
15. **Electrode tip**— Separation between electrode tip and lead body.
16. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
17. **DF-1 terminal pin**— Loss of sensing, loss of pacing, loss of defibrillation output. Compromised insulation and/or conductor integrity from sharp or excessive bending. Improvement implemented.
18. **Yoke component**— Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.
19. **Serial number label**— Loss of sensing, loss of pacing. Broken serial number label due to either sharp bend away from header at implant or repetitive movement during implant.
20. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
21. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
22. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
23. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
24. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.
25. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.

26. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.

27. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.

28. **Non-patterned, Insulation**— Lead insulation breach (including damage due to lead-on-lead or lead-on-anatomy contact, clavicle fatigue or crush) where the root cause is not associated with other malfunctions.

31. **Non-patterned, Crimp, Weld, Bond**— Interruption in conductor or lead body associated with a point of connection where the root cause is not associated with other malfunctions.

32. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.

33. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-on-lead or lead-on-can contact, or due to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.

34. **Extracardiac fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue near suture sleeve, not including clavicle-first rib damage, leading to discontinuity of conductor.

35. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.

36. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.

37. **Weld fracture**— Noise, loss of sensing. Fractured weld.

38. **Conductor cable fracture**— High impedance, potential loss of pacing and defibrillation therapy. Fractured high-voltage cable. Improvement implemented.

39. **Inner conductor break**— High impedance, loss of capture, loss of sensing. Inner conductor break. Commonly associated with helix extension/retraction difficulties at implant.

U.S. Chronic Lead Complications (Occurring After the First Month of Service)

Boston Scientific strives to provide meaningful detail in describing the performance of our products. U.S. Chronic Lead Complications are reported in compliance with ISO 5841-2: 2014 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. To be included in the Chronic Lead Complications table, a lead must be successfully implanted, with clinical observations (as listed in the table) occurring after the first month of implant, and have been removed from service surgically or electronically. The lead either was not returned for analysis, or was returned but had no confirmation of a malfunction.

While multiple complications are possible for any given lead, only one complication is reported per lead. The complication reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Chronic Lead Complications are included in the calculation of survival probability. Complications for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are provided.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	127000	30	105	97	27	2	1	3	3	0	8
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	4000	0	1	3	2	0	0	0	0	0	1
INGEVITY Passive Fixation 7631/7632/7731/7732	7000	0	1	2	1	0	0	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	72	786	851	729	319	90	162	397	0	65
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	189000	4	339	208	186	39	21	161	183	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	461000	21	549	672	349	88	90	413	343	0	44
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	62000	1	100	308	110	11	19	59	36	0	8
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	15000	1	89	19	37	12	4	14	16	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	52000	0	225	75	84	63	16	73	96	0	4

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Spiral L 4677/4678	5000	0	0	2	0	0	0	0	0	0	2
ACUITY X4 Spiral S 4674/4675	13000	1	0	9	0	0	0	0	0	0	2

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Straight 4671/4672	9000	0	0	7	1	0	0	0	2	0	7
ACUITY Steerable 4554/4555/4556	29000	2	27	404	41	3	2	8	26	0	97
ACUITY Spiral 4591/4592/4593	23000	0	15	255	30	1	1	3	6	0	151
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	2	30	257	42	3	2	10	12	0	92
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	2	287	1099	252	8	6	63	89	0	472
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	63	397	105	3	1	47	32	0	262

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	63000	16	25	75	18	17	8	6	10	8	4
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	3000	0	1	5	0	3	0	0	3	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	81000	15	28	90	27	18	9	5	8	17	8
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	2000	0	0	2	0	1	0	0	1	0	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0177 0184/0185/0186/0187	287000	28	426	349	127	507	65	99	223	193	28
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	4	95	64	48	86	7	34	146	32	6
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	32000	9	52	43	21	44	2	7	29	33	3
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	3	5	1	3	0	1	3	2	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401, 3501	22000	0	0	3	0	8	0	3	0	0

Longitude Surveillance Registry	Leads Enrolled	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Spiral 4591/4592/4593	1383	0	0	22	2	0	0	0	0	0	10
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	741	0	0	0	0	0	0	0	1	1	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	850	0	0	1	1	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1104	0	1	1	1	1	1	0	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	924	0	1	1	0	0	0	0	0	0	0

U.S. Acute Lead Observations

Boston Scientific strives to provide meaningful detail reflective of real-world product experience. In the first weeks following lead implantation, physiologic responses and lead performance can vary until chronic lead stability is attained. Acute lead performance may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques.

Because acute implant time contributes to overall clinical experience. Boston Scientific provides specific information regarding acute lead performance. To be included in the Acute Lead Observations table, a lead must first be successfully implanted, with clinical observations occurring within the first month of implant. These reports may or may not have resulted in clinical action and/or product return to Boston Scientific. The categories are consistent with the AdvaMed guidance for *Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads* . Although multiple observations are possible for any given lead, only one observation is reported per lead. The observation reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Acute Lead Observations are not included in calculation of lead survival probability. Observations for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are included.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	127000	158	239	327	141	33	32	9	96	0	27
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	4000	0	0	11	4	0	0	0	0	0	1
INGEVITY Passive Fixation 7631/7632/7731/7732	7000	1	2	12	7	1	3	1	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	239	196	1362	432	75	88	57	214	0	51
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	189000	15	14	449	178	9	26	25	40	0	21
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	461000	83	86	713	262	114	100	62	253	0	44
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	62000	1	18	450	95	8	29	17	22	0	11
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	15000	1	4	34	16	1	3	6	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/4473/4474	52000	3	18	107	28	9	10	21	13	0	6

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Spiral L 4677/4678	5000	1	0	10	6	3	0	0	3	0	12
ACUITY X4 Spiral S 4674/4675	13000	3	0	22	9	1	0	0	28	0	30

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Straight 4671/4672	9000	1	0	24	15	2	0	0	19	0	24
ACUITY Steerable 4554/4555/4556	29000	1	3	327	50	25	2	7	134	0	243
ACUITY Spiral 4591/4592/4593	23000	5	4	216	68	8	1	9	38	0	244
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	4	2	274	38	12	2	8	47	0	188
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	13	10	937	135	46	9	27	200	0	731
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	19	34	0	186

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	63000	57	33	188	90	75	12	7	85	23	12
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	3000	2	0	9	1	3	0	0	18	2	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	81000	71	43	212	84	97	23	9	96	82	27
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	2000	1	1	3	2	1	1	0	20	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287000	149	189	649	170	367	54	70	361	234	80
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	8	3	106	45	57	8	5	178	17	2
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	32000	30	16	79	31	34	14	3	56	121	9
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	0	3	1	1	2	0	11	1	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010/3401/3501	22000	1	0	15	0	225	18	1	83	1

Longitude Surveillance Registry	Leads Enrolled	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Spiral 4591/4592/4593	1383	0	0	12	10	1	0	0	3	0	48
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	741	0	0	1	0	1	0	1	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	850	0	2	12	0	0	0	1	2	0	3
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1104	6	1	9	7	5	3	0	2	1	2
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	924	0	0	1	1	0	0	0	0	0	0

Before/During Implant Procedure - Worldwide Malfunctions: Leads

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling is not reported as device malfunction here.
The Conductor category includes any conductor break or damage with complete or intermittent loss of continuity that could interrupt current flow, including clavicle fatigue or crush damage. The Insulation category includes any lead insulation breach, such as damage due to lead-on-lead or lead-on-anatomy contact, or clavicle fatigue or crush. The Crimp/Weld/Bond category includes any interruption in the conductor or lead body associated with a point of connection. The Other category includes malfunctions for which the root cause does not fit within other categories or has not yet been determined. The Labeling and Packaging categories include product identification issues and damage to sterile packaging, respectively. The Implant Accessory category includes lead malfunctions due to catheter, guidewire or sheath issues.

CRT Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ACUITY X4 Spiral L 4677/4678	14,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	31,000	0	0	0	3	0	0	0
ACUITY X4 Straight 4671/4672	26,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	64,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	44,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	43,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	178,000	0	5	0	7	1	1	1
EASYTRAK 4510/4511/4512/4513/4535/4536/4537/4538	53,000	0	0	0	4	0	0	3

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation 0658/0695/0696	11,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	44,000	3	0	0	1	0	0	0
ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation 0655/0685/0686	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation 0654/0682/0683	3,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276/0295/0296	102,000	0	0	0	65	0	1	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266/0285/0286	9,000	0	0	0	4	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Active Fixation 0292/0293	129,000	0	0	0	23	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Passive Fixation 0282/0283	5,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	375,000	0	0	44	489	0	3	14
ENDOTAK RELIANCE Dual Coil Passive Fixation 0147/0148/0149/0174/0175/0176/0177	109,000	0	1	3	87	0	3	0
ENDOTAK RELIANCE Single Coil Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	70,000	0	0	7	63	0	1	3
ENDOTAK RELIANCE Single Coil Passive Fixation 0127/0128/0170/0171/0172/0173	8,000	0	0	0	2	0	0	0

S-ICD Electrodes/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401, 3501	38,000	0	0	1	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	362,000	1001	0	0	1773	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	36,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	42,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	185,000	0	0	10	122	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	290,000	0	0	55	605	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	527,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	712,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	299,000	0	3	1	129	6	19	0
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	104,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	141,000	0	1	1	25	1	6	0

*Counts consist of Boston Scientific and Intermedics co-branded pacing leads data.

Product Advisories

A Product Advisory is a voluntary letter issued to inform physicians of an anomalous device behavior identified by Boston Scientific's Quality System. A Product Advisory is issued when there is a material elevation in risk to patient safety with potential for compromised lifesaving therapy, or when Boston Scientific can provide meaningful guidance to improve patient outcomes or device performance. Boston Scientific considers many perspectives in the decision to issue a Product Advisory, including internal expertise and guidance from an independent Patient Safety Advisory Board (PSAB).

This report section includes summaries of Product Advisories for which significant, active U.S. device populations exist. In general, this includes advisories for which the estimated active U.S. advisory population is at least 200. Physician and patient letters, as well as Advisory Updates, are available at www.bostonscientific.com. With respect to the number of reported events listed in the summaries below, Boston Scientific recognizes that the actual number of clinical malfunctions may be greater than the number reported. Additionally, rate projections are provided with the acknowledgment that predictive modeling is inherently uncertain due to its dependence on the device age distribution of reported events and resultant statistical approximations and assumptions. Advisory notifications may vary by geography, based upon local regulatory requirements. Please contact the local Boston Scientific office for more information. Not all products may be approved for use in all geographies, as product approval is geography specific.

PRODUCT	ORIGINAL COMMUNICATION **June 2017 — S-ICD Memory Corruption**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **S-ICD** Models 1010, A209, A219 S-ICD Memory Corruption, Physician Letter, Jun 29, 2017 S-ICD Memory Corruption, Patient Letter, Jun 29, 2017 S-ICD Software v4.04 Programmer Commands and Memory Corruption August 2017	Voluntary Physician Advisory FDA Classification: Class II This advisory discusses a single, isolated S-ICD event that resulted in a device-related patient death. Boston Scientific engineers have determined that this patient's S-ICD repeatedly delivered an atypical amount of energy (similar to the arrhythmia induction function) because a specific memory location was corrupted by radiation within the environment. This repeated atypical energy delivery prevented S-ICD arrhythmia detection/treatment and ultimately contributed to the patient death. *Estimated Rate of Occurrence* This experience represents one (1) observed event in approximately 37,000 S-ICDs distributed worldwide. Given the rarity of this single event observed to date, a precise projection of occurrence cannot be derived with confidence. Engineering analysis of S-ICD device memory design and recorded instances of SEUs in fielded devices was conducted during our root cause investigation of this event. Based on this analysis, the probability of corruption of the specific location in memory that produces this device behavior within an S-ICD was determined to be approximately 1 in 300,000 over five years.
	CURRENT STATUS **10-Oct-17** This experience represents one (1) observed event in approximately 39,100 S-ICDs distributed worldwide. *Estimated Rate of Occurrence* The probability of corruption of the specific location in memory that produces this device behavior within an S-ICD was determined to be approximately 1 in 300,000 over five years.
	CURRENT RECOMMENDATION **10-Oct-17** In consultation with our Patient Safety Advisory Board, Boston Scientific recommends NO changes to clinical follow-up due to this single event. Specifically, for patients with S-ICD systems: • Continue using the S-ICD system to detect and treat life-threatening ventricular tachyarrhythmias; • Keep scheduled LATITUDE™ and/or in clinic follow-ups; and • Follow the precautions identified in the S-ICD user's manual when radiation therapy is prescribed. Furthermore, Boston Scientific does NOT recommend the following: • Early or off-cycle follow-ups are not recommended. This type of memory corruption cannot be detected, thus additional S-ICD checks do not reduce the potential for this device behavior. • Prophylactic S-ICD replacement or explant is not recommended. The risks associated with such an additional surgical procedure significantly outweigh the risk of reoccurrence of this device behavior. Until the software mitigation update is available, this S-ICD behavior represents an additional, small risk that should be considered when evaluating the relative risks associated with all available ICD therapy options. Boston Scientific is now releasing programmer software version 4.04 to address the behavior for S-ICDs and a local Boston Scientific representative will arrange to update each programmer. This advisory no longer applies after an S-ICD is interrogated by any programmer updated with version 4.04 software. Recommendations for S-ICD and Programmers • Confirm all Model 3200 S-ICD programmers are upgraded with version 4.04 software. • Once your Model 3200 S-ICD programmers are upgraded, perform a standard in-clinic S-ICD followup for all patients implanted with an S-ICD at their earliest convenience. The January 2017 recommendation to perform a second interrogation is no longer required. Note: The programmer will upgrade each S-ICD's software which takes less than 5 minutes. • Thereafter, standard in-clinic S-ICD follow-up checks may resume at normal frequency with programmers upgraded with version 4.04 software. Note: When an S-ICD's software has been upgraded, it can only be interrogated with programmers installed with version 4.04 or greater software. Appendix A shows how the software model and version number can be identified through the programmer or an S-ICD summary report.

PRODUCT	ORIGINAL COMMUNICATION **January 2017 — S-ICD Programmer Commands**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **S-ICD Programmer** Model 3200 S-ICD Programmer Commands, Physician Letter, May 18, 2017 S-ICD Programmer Commands, Physician Letter, Jan 12, 2017 S-ICD Programmer Commands, Patient Letter, Jan 12, 2017 S-ICD Software v4.04 Programmer Commands and Memory Corruption August 2017	Voluntary Physician Advisory FDA Classification: Unclassified This advisory discusses the potential for radio frequency (RF) interference to alter wireless communication from a Model 3200 S-ICD programmer, which in rare instances may cause an S-ICD to perform an unintended command. This behavior can only occur during an active, in-clinic interrogation/programming session with the Model 3200 S-ICD programmer. There is no risk of this behavior occurring when the LATITUDE Patient Management System communicates with an S-ICD in an ambulatory setting. Both the programmer and the S-ICD check the validity of telemetry commands using an algorithm intended to detect whether these commands have been altered. In nearly all instances, invalid commands are rejected. In rare instances, interference may go undetected and alter communications from the programmer. This can potentially result in the S-ICD performing an induction, utilizing temporary parameters that impair the S-ICD from detecting or treating a tachyarrhythmia during the active telemetry session, or disabling therapy in the permanent programming mode such that therapy will be unavailable after the telemetry session is ended. Because the programmer display may not match device programming when this behavior occurs, ending the session and re-interrogating the S-ICD is an effective means to check the permanently programmed device parameters. The potential for this behavior to occur during this brief re-interrogation is extremely remote. All communications between the programmer and S-ICD remain secure. This behavior is not related to a cybersecurity vulnerability. The LATITUDE Patient Management System (remote monitoring) is not subject to this behavior and is a reliable way to check S-ICD settings and performance. *Estimated Rate of Occurrence* For the EMBLEM S-ICD, the probability of serious adverse consequences is estimated to be 1 in 25,000 at 5 years. For the SQ-RX S-ICD, the probability of serious adverse consequences is estimated to be 1 in 200,000 at 5 years.
	CURRENT STATUS **10-Oct-17**
	Eleven observations of unintended programming commands or data changes have been observed within the population of approximately 27,100 EMBLEM and EMBLEM MRI S-ICDs. Three observations of unintended programming commands or data changes have occurred with the SQ-RX™ S-ICD. There have been no reported patient deaths associated with this advisory. *Estimated Rate of Occurrence* For the EMBLEM S-ICD, the probability of serious adverse consequence is estimated to be 1 in 25,000 at 5 years. For the SQ-RX S-ICD, the probability of serious adverse consequences is estimated to be 1 in 200,000 at 5 years.
	CURRENT RECOMMENDATION **10-Oct-17**
	Boston Scientific is now releasing programmer software version 4.04 to address the behavior for S-ICDs and a local Boston Scientific representative will arrange to update each programmer. This advisory no longer applies after an S-ICD is interrogated by any programmer updated with version 4.04 software. Recommendations for S-ICD and Programmers • Confirm all Model 3200 S-ICD programmers are upgraded with version 4.04 software. • Once your Model 3200 S-ICD programmers are upgraded, perform a standard in-clinic S-ICD followup for all patients implanted with an S-ICD at their earliest convenience. The January 2017 recommendation to perform a second interrogation is no longer required. Note: The programmer will upgrade each S-ICD's software which takes less than 5 minutes. • Thereafter, standard in-clinic S-ICD follow-up checks may resume at normal frequency with programmers upgraded with version 4.04 software. Note: When an S-ICD's software has been upgraded, it can only be interrogated with programmers installed with version 4.04 or greater software. Appendix A shows how the software model and version number can be identified through the programmer or an S-ICD summary report. Until a programmer software update is available for SQ-RX S-ICDs, Boston Scientific recommends the following: • Consider reducing the frequency of in-clinic checks while following medical society guidelines. The SQ-RX S-ICD is not compatible with the LATITUDE Patient Management System. • When performing a programming change or device check of an SQ-RX using a Model 3200 S-ICD Programmer: – Ensure external defibrillation equipment and medical personnel skilled in CPR are available during in-office follow-up testing and do not leave the patient unattended. – Place the telemetry wand directly over the S-ICD at all times and increase the distance between any source of interference and the programmer and S-ICD as much as possible. – Minimize the duration of programmer communications and end the programmer telemetry session promptly after completion. • When the programmer is communicating with an SQ-RX S-ICD, it is possible that this behavior may alter temporary parameters without the user's knowledge. Altering of temporary parameters may result in an inability for the SQ-RX S-ICD to detect a tachyarrhythmia or an inappropriate detection of a heart rhythm. – To initiate a defibrillation therapy, press the Rescue Shock icon and follow screen prompts. – To abort an inappropriate shock, press the Abort button while the S-ICD is charging • When the programming change or device check is complete, confirm SQ-RX S-ICD settings by performing the following steps: – End the original telemetry session – Initiate a new telemetry session – Print a device Summary Report (see Appendix B)

PRODUCT

A serialized search tool to determine if a specific device is affected by this product advisory is available here:

Device Lookup Tool

COGNIS
Models N106/N107/N108/N118/ N119/N120/P106/P107/P108

TELIGEN VR
Models E102/E103/F102/F103

TELIGEN DR
Models E110/E111/F110/F111

Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014

Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014

Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013

ORIGINAL COMMUNICATION **Aug 2013 and Sep 2014 — Low Voltage Capacitor**

Voluntary Physician Advisory
FDA Classification August 2013: Class II
FDA Classification September 2014: Class II

In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. It also informed physicians how to identify and respond to a Safety Architecture low voltage alert. In September 2014, a second subset of devices was identified that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset. The second communication also discussed improvements to Safety Architecture's low voltage alert, which were released through a programmer software update.

The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping.

The most common alert is a yellow programmer screen that states, "Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003". LATITUDE issues a corresponding yellow alert (nominally configured "On"). In other instances, diminished LV capacitor performance can result in an early "Explant" battery status indicator (ERI) and a replacement window that may be less than 3 months. Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry.

Advisory population
Approximately 22,800 devices identified in the August 2013 communication remain in service. In September 2014, Boston Scientific identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.

CURRENT STATUS **10-Oct-17**

Advisory devices have not been available for implant for more than seven years.

Confirmed Malfunctions (worldwide)
5,014 malfunctions have been confirmed from the advisory population. Approximately 36,000 devices from the advisory populations remain in service.

There has been one reported patient death due to complications with the replacement of an advisory device.

Projected Rate of Occurrence

• COGNIS CRT-D and TELIGEN ICD advisory population - The rate of occurrence is 2.9% at 60 months and 6.0% at 72 months. The projected rate of occurrence is 8.7% at 84 months. The potential for life-threatening harm from loss of therapy is approximately 1 in 200,000 (0.0005%) at 60 months.

• COGNIS CRT-D and TELIGEN ICD populations (advisory and non-advisory) - The overall rate of occurrence is approximately 1% at 60 months. Since notifying customers of this behavior in September 2014 and improving the Safety Architecture voltage alert, the portion of malfunctions with compromised therapy has decreased to approximately 2%. The potential for life-threatening harm from loss of therapy is approximately 1 in 500,000 (0.0002%) at 60 months.

• INCEPTA, ENERGEN and PUNCTUA CRT-Ds and ICDs (non-advisory) - The projected rate is approximately 1% at 60 months. The portion of malfunctions with compromised therapy is approximately 0.2%. The potential for life-threatening harm from loss of therapy is approximately 1 in 5,000,000 (0.00002%) at 60 months.

CURRENT RECOMMENDATION **10-Oct-17**

Updated Software
In 2014 BSC released software that enhances the effectiveness of the Safety Architecture tools later in device life. When the software was introduced, BSC recommended an in-clinic follow-up with an updated programmer at first opportunity, but within 3 months for patients within the advisory population. In-clinic interrogation with a current programmer automatically downloads Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted.

LATITUDE Patient Management System
Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if/when scheduled checkups have not occurred. Verify that the yellow alert "Voltage was too low for projected remaining capacity" is configured "On".

Additional Recommendations

- After a device has been upgraded with new software, Boston Scientific recommends normal device monitoring as described in device labeling.
- Device replacement is not recommended for advisory devices displaying normal behavior.
- Promptly investigate alerts, device beeping, and unanticipated replacement indicator messages.
- Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens. Technical Services can facilitate an evaluation of device information downloaded from a recent in-clinic or remote LATITUDE interrogation, which may help to clarify available replacement time.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **01-Dec-09 — Subpectoral Implant**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: Class II This advisory is limited to devices identified in the product model list that were implanted subpectorally. Devices implanted subcutaneously are not included in this advisory.
This advisory is limited to those models listed below implanted subpectorally.	Boston Scientific has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy.
COGNIS Models N106/N107/N108/N118/N119 P106/P107/P108 **TELIGEN VR** Models E102/F102 **TELIGEN DR** Models E110/E111/F110/F111	A weakened header bond can result in one or more of the following device behaviors: – Significant changes in measured lead impedance – Noise on real-time or stored electrograms – Intermittent inhibition of pacing – Inappropriate anti-tachy pacing or shock therapy – Loss of pacing therapy – Loss of anti-tachy pacing and shock therapy No patient deaths related to this behavior have been reported. Patients have required early device replacement due to inappropriate shocks and/or noise induced by pocket manipulation or arm movement.
Subpectoral Implant 2009 Physician Letter, Dec 01, 2009 Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	*Rate of Occurrence* The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. The following factors may also impact the risk of failure if implanted in a subpectoral location: – Exact location of the patient's ribs relative to the device – Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients) – Activity level and/or occupation of the patient (risk may increase for more active patients)
	CURRENT STATUS **10-Oct-17**
	Reported events (worldwide) Ninety-seven (97) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. There have been no reported patient deaths associated with this advisory. *Rate of Occurrence* An estimated 10% of COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral position. The rate of occurrence for subpectoral implants of COGNIS advisory devices is 1.95% at 60 months. The rate of occurrence for subpectoral implants of TELIGEN advisory devices is 0.53% at 60 months.
	CURRENT RECOMMENDATION **10-Oct-17**
	If a patient's device was implanted subcutaneously, it is excluded from this advisory and no change to current patient management is recommended. **For affected devices implanted in a subpectoral location:** – Follow patient at least once every three months as recommended in device instructions for use. – Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation. – Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **23-Jun-06 and 24-Aug-06— Low Voltage Capacitor**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **INSIGNIA Ultra SR** Models 1190/1390 **INSIGNIA Ultra DR and Ultra DR Downsize** Models 1291/1491/1290/1490 **INSIGNIA Entra SR** Models 1195/1198/1395/1398 **INSIGNIA Entra DR (downsize)** Models 1296/1466 **INSIGNIA Entra DR** Models 1294/1295/1494/1495 **INSIGNIA Entra SSI** Models 0484/0485/1325/1326 **INSIGNIA Entra DDD** Models 0985/0986/1426 **INSIGNIA Plus SR** Models 1194/1394 **INSIGNIA Plus DR and Plus DR Downsize** Models 1297/1467/1298/1468 **INSIGNIA AVT** Models 0482/0882/0982 1192/12921392/1428/1432/1492 **CONTAK RENEWAL TR / TR2** Models H120/H125/H140/H145 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY 2 VR/DR** Models T175/T165 **VITALITY DR HE** Model T180 **VITALITY DS VR/DR** Models T135/T125 **VITALITY VR/DR and EL** Models 1870/1871/T127 **VENTAK PRIZM 2 VR/DR** Models 1860/1861 Low Voltage Capacitor, Physician Low Voltage Capacitor, Patient Letter, Low Voltage Capacitor, Physician Letter, Jun 23, 2006	Voluntary Physician Advisory FDA Classification: Class II Devices within a well-defined subset manufactured using low-voltage capacitors from a single component supplier may perform in a manner that leads to device malfunction, including intermittent or permanent loss of output or telemetry, or premature battery depletion. At the time of the original June 23, 2006 communication, approximately 49,800 devices had been distributed, and approximately 27,200 devices had been implanted worldwide. Boston Scientific initiated retrieval of all non-implanted devices within this subset from hospital and sales force inventory. An Advisory Update was issued on August 24, 2006, with a revised estimation of the implanted population to be approximately 31,000. All product currently being shipped and available for implant is not susceptible to this issue. *Reported Events (worldwide)* At the time of the original June 23, 2006 communication, a total of five (5) devices had been confirmed to have malfunctioned. As reported in the August 24, 2006 Advisory Update, five (5) additional malfunctions were confirmed since the original June 23, 2006 communication. A total of 10 confirmed malfunctions represented 0.032% of the implanted population of approximately 31,000 devices. Seven (7) of 10 malfunctions were identified while implanted, and three were identified prior to the implant procedure. There were no reports of patient death associated with this issue. There were a total of three (3) reports of patients experiencing syncope associated with loss of pacing. *Projected Rate of Occurrence* While a statistically significant projection of expected failures for implanted devices was not possible, testing suggested that the frequency of new malfunctions would continue to decrease in the future. CURRENT STATUS **10-Oct-17** *Confirmed Malfunctions (worldwide)* 46 malfunctions have been confirmed from the advisory population. 35 of these were identified while implanted. There were an estimated 32,000 advisory devices implanted. 11 malfunctions were identified prior to implantation. There have been no reported patient deaths associated with this advisory. No devices currently being distributed are susceptible to this malfunction mode. *Projected Rate of Occurrence* The rate of occurrence is projected to range between 0.10% and 0.22%. CURRENT RECOMMENDATION **10-Oct-17** Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged. – Normal follow-up. – Physicians should consider the low and declining failure rate in addition to the unique needs of individual patients when making medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness. – Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation. **Device Behavior** **Pacemakers: INSIGNIA** – Intermittent or permanent loss of pacing output – Inability to interrogate – Erased values in Daily Measurements – ERT or EOL indicator message displayed earlier than expected – A gas gauge less than BOL within six months of implant
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **12-May-06 and 04-Jan-08 Subpectoral Implant**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool *This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs..* **CONTAK RENEWAL 4 HE** Models H197/H199 **CONTAK RENEWAL 4** Models H190/H195 **CONTAK RENEWAL 4 AVT / AVT HE** Models M170/M175/M177/M179 **CONTAK RENEWAL 3 HE** Models H177/H179 **CONTAK RENEWAL 3** Models H170/H175 **CONTAK RENEWAL 3 AVT / AVT HE** Models M155/M159 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY DR HE** Model T180 **VITALITY EL** Model T127 **VITALITY DR+** Model 1872	Voluntary Physician Advisory FDA Classification: Class II Accelerated life testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction only if the device is implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion). An anterior/posterior (AP) radiograph can be used to determine device orientation. Due to component location, damage associated with this subpectoral failure mode will not occur in a subcutaneous position or in a position with the serial number facing up. This failure mechanism can result in one or more of the following device behaviors: – Loss of shock therapy – Loss of pacing therapy (intermittent or permanent) – Loss of telemetry communications – Beeping (16 tones every six hours), and a programmer warning screen upon interrogation *Reported Events* Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism. *Rate of Occurrence* The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.
	CURRENT STATUS **10-Oct-17**
	Confirmed Malfunctions (worldwide) May 12, 2006 Population Nineteen (19) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation. January 4, 2008 Population Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months.
	CURRENT RECOMMENDATION **10-Oct-17**
Subpectoral Implant, Physician Letter, Jan 04, 2008 Subpectoral Implant, Patient Letter, Dec 01, 2009	Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication. – For patients implanted with a model listed in the advisory, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory. – For subpectoral implants, use an AP radiograph to determine specific device orientation. - If the leads exit the pulse generator in a counter clockwise direction (serial number facing away from the ribs), this advisory does not apply and no change to current patient management is necessary. If the device is in a susceptible orientation (serial number facing the ribs): – Advise patient of the potential for device failure. – Follow patient at 3 month intervals in accordance with device labeling. – Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy. – For future implants, when considering subpectoral implantation, orient the device with the serial number facing away from the ribs.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **22-Sep-05 — Crystal Timing Component**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **INSIGNIA Ultra SR** Models 1190/1390 **INSIGNIA Ultra DR and Ultra DR Downsize** Models 1291/1491/1290/1490 **INSIGNIA Entra SR** Models 1195/1198/1395/1398 **INSIGNIA Entra DR (downsize)** Models 1296/1466 **INSIGNIA Entra DR** Models 1294/1295/1494/1495 **INSIGNIA Entra SSI** Models 0484/0485/1325/1326 **INSIGNIA Entra DDD** Models 0985/0986/1426 **INSIGNIA Plus SR** Models 1194/1394 **INSIGNIA Plus DR and Plus DR Downsize** Models 1297/1467/1298/1468 **INSIGNIA AVT** Models 0482/0882/0982 1192/12921392/1428/1432/1492	Voluntary Physician Advisory FDA Classification: Class II Two separate failure modes were identified that may result in intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, and/or reversion to VVI mode or appearance of a Reset warning message upon interrogation. The root cause of the first failure mode is foreign material within a crystal timing component. As of the December 12, 2005 Advisory Update, root cause had been identified as a microscopic particle within the crystal timing component. *Reported Events* Failure Mode 1—As of September 6, 2005, 36 malfunctions have been confirmed out of 49,500 devices distributed worldwide (0.073%). The majority of malfunctions occurred early in life, with a mean implant time of seven (7) months. There were no reported patient deaths. The supplier of the crystal timing component used in this subset of devices has eliminated foreign material within the crystal chamber, and no malfunctions were observed in any devices shipped after March 12, 2004. Failure Mode 2—As of September 6, 2005, 16 malfunctions were confirmed out of 341,000 devices distributed worldwide (0.0047%). All 16 devices exhibited a no-output condition at the implant procedure or during pre-implant testing. There were no reported patient deaths. *Rate Projection* Failure Mode 1—As of the September 22, 2005 communication, Modeling, based on field experience and statistical analysis, predicted the malfunction rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime.
	CURRENT STATUS **10-Oct-17**
	Confirmed Malfunctions (worldwide) Failure Mode 1— 62 malfunctions out of approximately 49,500 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory. Failure Mode 2— 26 malfunctions out of approximately 257,000 (0.010%) devices distributed have been confirmed. Twenty-two (22) malfunctions were identified before or during the implant procedure and four (4) were identified after implant. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 4,000 is projected to range between 0.027% and 0.038%.
	CURRENT RECOMMENDATION **10-Oct-17**
Crystal Timing Component, Physician Letter, Dec 12, 2005 Crystal Timing Component, Patient Letter, Oct 03, 2005 Crystal Timing Component, Physician Letter, Sep 22, 2005	Failure Mode 1— Patient management recommendations from the September 22, 2005 physician communication remain unchanged. Failure Mode 2— Patient management recommendations supersede those originally communicated on September 22, 2005. – Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices. – Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.
	Standard Warranty program available, please contact your local representative for terms and conditions.

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